IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

UNITED STATES OF AMERICA; and THE STATES OF CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, LOUISIANA, MARYLAND, MICHIGAN, MINNESOTA, NEVADA, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, WISCONSIN; and THE COMMONWEALTHS OF MASSACHUSETTS and VIRGINIA; and THE DISTRICT OF COLUMBIA; ex rel. AMANDA WU Plaintiff and Relator v. ALERE SAN DIEGO, INC. f/k/a Biosite, Inc.; and ALERE, INC. f/k/a Inverness Medical Innovations, Inc. Defendants.	CIVIL NO. L-11-1808 **FILED IN CAMERA AND UNDER SEAL PURSUANT TO 31 U.S.C. § 3730(b)(2)**

FIRST AMENDED FALSE CLAIMS ACT COMPLAINT

1. AMANDA WU ("Relator") brings this action on behalf of the United States of America ("United States") for treble damages and civil penalties arising from Defendants' conduct in violation of the Federal Civil False Claims Act, 31 U.S.C. § 3729, *et seq.* ("FCA").

2. This action is also brought under the respective *qui tam* provisions of False Claims Acts (or similarly named) on behalf of the States of California, Colorado, Connecticut, Delaware,

Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Maryland, Michigan, Minnesota, Nevada, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Wisconsin, the Commonwealths of Massachusetts and Virginia, and the District of Columbia. These states, together with the United States, are hereafter when collectively referred to as the Government.

3. The pervasive unlawful conduct described herein began at least six (6) years before the filing of this Complaint, and has continued to date.

OVERVIEW

4. Product safety is the issue in this case. For years, Defendants have produced defective FDA-approved products, which defects have direct patient consequences.

5. Healthcare providers rely on Defendants' cardiovascular lab testing products to guide their medical-decision making. Classified by Federal Food & Drug Administration (FDA) as "medical devices," these diagnostic tools are oftentimes used to treat fragile, unstable outpatient or hospitalized patients at critical moments of care, driving decisions involving additional tests, treatments, and hospitalizations. If the devices are unreliable, then both biologic false positive (FP) and false negative (FN) results may occur, leading to over-diagnoses or missed diagnoses. Governmental agencies and others rely on Defendants' TOX Drug Screen to determine the presence of drugs of abuse in individuals. A FP or FN can result in an injustice: an individual's loss of liberty; and a multitude of other adverse consequences.

6. This case is about the wholesale unreliability of these devices – unreliability which Defendants have been well aware of for years. Instead of fixing the problem, Defendants watered down the finished product release specifications, such that the device characteristics were

significantly altered and no longer resembled the basis upon which the FDA cleared the devices in the 510(k) pre-market notification process. The result has been substandard, defective products.

FEDERAL JURISDICTION AND VENUE

7. The acts proscribed by 31 U.S.C. § 3729 *et seq*. and complained of herein occurred in the District of Maryland and elsewhere, as the Defendants do business in the District of Maryland and throughout the United States. Therefore, this Court has jurisdiction over this case pursuant to 31 U.S.C. § 3732 (a), as well as under 28 U.S.C. § 1345. This Court has supplemental jurisdiction over this case for the claims brought on behalf of the States (referenced in paragraph 2) pursuant to 31 U.S.C. § 3732(b) and/or 28 U.S.C. § 1367, inasmuch as recovery is sought on behalf of said States which arises from the same transactions and occurrences as the claims brought on behalf of the United States.

8. Venue is proper in this District pursuant to 31 U.S.C. § 3732(a), and 28 U.S.C. § 1391 (b) and (c), because the Defendants transact business in this District and one or more of the acts committed by the Defendants and proscribed by 31 U.S.C. § 3729 occurred in this District.

PARTIES

9. The United States funds the provision of medical care for eligible citizens through federally-funded healthcare programs such as Medicare, Medicaid, TRICARE, and other agencies and programs, acting through the Centers for Medicare & Medicaid Services (CMS) within the U.S. Department of Health and Human Services, the Department of Defense, and other federal agencies.

These federally-funded healthcare programs are hereinafter collectively referred to as "Government Healthcare Programs."

10. Relator, AMANDA WU, is a resident of the State of California. Relator brings this action based upon her independent and direct knowledge.

11. Defendant Alere San Diego, Inc. ("Alere SD") formerly known as Biosite, Inc., is a Delaware corporation with its principal place of business in San Diego, California. In 2007, Biosite Incorporated (now known as "Alere San Diego"), was acquired by Inverness Medical Innovations, Inc. (now known as Alere Inc. (NYSE:ALR)).

12. Defendant Alere, Inc., formerly known as Inverness Medical Innovations, Inc., has its principal place of business in Waltham, Massachusetts, and is the parent company of Alere SD. It is a Delaware corporation, which changed its name to Alere, Inc. effective July 15, 2010.

13. Both Alere SD and Alere, Inc. shall hereinafter be collectively referred to as "Defendants."

FALSE CLAIMS ACT

14. The False Claims Act (FCA) was originally enacted in 1863, and it was substantially amended in 1986 by the False Claims Amendments Act, Pub.L. 99-562, 100 Stat. 3153. Congress enacted the 1986 amendments to enhance and modernize the Government's tools for recovering losses sustained by frauds against it, after finding that federal program fraud was pervasive. The amendments were intended to create incentives for individuals with knowledge of Government frauds to disclose the information without fear of reprisals or Government inaction, and to encourage

the private bar to commit resources to prosecuting fraud on the Government's behalf.

15. The FCA provides that any person who presents, or causes to be presented, false or fraudulent claims for payment or approval to the United States, or knowingly makes, uses, or causes to be made or used false records and statements to induce the United States to pay or approve false and fraudulent claims, is liable for a civil penalty ranging from $5,500 up to $11,000 for each such claim, plus three times the amount of the damages sustained by the United States, 31 U.S.C. § 3729, *et seq*.

16. The FCA allows any person having information about false or fraudulent claims to bring an action for himself and the Government, and to share in any recovery. The FCA requires that the complaint be filed under seal for a minimum of 60 days (without service on the Defendant during that time). Based on these provisions, *qui tam* Plaintiff and Relator seek through this action to recover all available damages, civil penalties, and other relief for state and federal violations alleged herein.

FEDERAL HEALTHCARE PROGRAMS

17. The type and extent of reimbursement for diagnostic tests furnished to Government Healthcare Program beneficiaries depends upon (1) the particular Government Healthcare Program; and (2) whether the patient is being treated as an outpatient or inpatient.

18. The Medicare Program is administered by the Centers for Medicare & Medicaid Services ("CMS"), part of the United States Department of Health & Human Services ("HHS"), through private contractors. 42 U.S.C. §§ 1395h, 1395u. The contractors (usually insurance companies) are responsible for making an initial determination on claims under Part A or Part B on

the basis of regulations and other policies articulated by the Secretary. 42 U.S.C. § 1395ff(a)(1).

19. Medicare is a federally-funded health insurance program primarily benefitting the elderly. Medicare was created in 1965 when Title XVIII of the Social Security Act was adopted. The Medicare program is administered through CMS.

20. The Medicare program has four parts: Part A, Part B, Part C and Part D. Medicare Part A, the Basic Plan of Hospital Insurance, covers the cost of inpatient hospital services and post-hospital nursing facility care. Medicare Part B is a voluntary supplemental program, 42 U.S.C. § 1395j, that covers medical and other healthcare services, 42 U.S.C. § 1395k(a)(1), including "diagnostic laboratory tests." Medicare Part C covers certain managed care plans.

21. In 1965, the federal government also enacted the Medicaid Program. It is a cooperative undertaking between the federal and state governments to help the states provide health care to low-income individuals. The Medicaid Program pays for services pursuant to plans developed by the states and approved by the HHS Secretary through CMS. 42 U.S.C. §§ 1396a(a)-(b). States pay doctors, hospitals, pharmacies, and other providers and suppliers of medical items and services according to established rates. 42 U.S.C. §§ 1396b(a)(1), 1903(a)(1). The Federal Government then pays each state a statutorily established share of "the total amount expended ... as medical assistance under the State plan." See 42 U.S.C. § 1396b(a)(1). This federal-to-state payment is known as Federal Financial Participation ("FFP"). Over half of those enrolled in Medicaid are children, about a fifth are low-income parents; about a sixth are low-income individuals with disabilities and the remainder are low-income elderly (most of whom are also enrolled in Medicare).

22. TRICARE Management Activity, formerly known as CHAMPUS, is a program of

the Department of Defense that helps pay for covered civilian health care obtained by military beneficiaries, including retirees, their dependents, and dependents of active-duty personnel. 10 U.S.C. §§ 1079, 1086; 32 C.F.R. Part 199. TRICARE contracts with fiscal intermediaries and managed care contractors to review and pay claims, including claims submitted for diagnostic and laboratory tests.

23. Under the Medicare Act, 42 U.S.C. § 1395y(a)(1)(A), there is, an express fundamental condition of payment - "no payment may be made [under the Medicare statute] for any expenses incurred for items or services which . . . are not reasonable and necessary for the diagnosis or treatment of illness or injury." This condition links each Medicare payment to the requirement that the particular item or service be "reasonable and necessary." Medicaid, TRICARE and other federally funded programs restrict coverage under the same principle.

Medical Device Regulation

24. In general, medical device manufacturing is a heavily regulated industry, and rightfully so. The applicable statute empowering the FDA to promulgate regulations is found at 21 U.S.C. § 360j(f)(1)(A) and (B), and provides as follows:

> (A) The Secretary may, in accordance with subparagraph (B), prescribe regulations requiring that the methods used in, and the facilities and controls used for, the manufacture, pre-production design validation (including a process to access the performance of a device but not including an evaluation of the safety or effectiveness of a device), packing, storage, and installation of a device conform to current good manufacturing practice, as prescribed in such. regulations, to assure that the device will be safe and effective and otherwise in compliance with this chapter.

25. The Federal Food Drug & Cosmetic Act categorizes medical devices into one of three classes, depending on the risk they pose to the public. Class I devices are subject to "general controls," the lowest level of federal oversight, and include devices such as elastic bandages and examination gloves. 21 U.S.C. § 360c(a)(1)(A) Class II devices are subject to additional oversight called "special controls." 21 U.S.C. § 360c(a)(1)(B). Finally, Class III devices are subject to the highest level of federal oversight, or "premarket approval."

26. The devices in this case are Class II devices, which required approval via the 510(k) process. A 510(k) Pre-Market submission is made to the FDA to demonstrate that a device to be marketed is at least as safe and effective, that is, substantially equivalent, to a legally marketed device (21 CFR § 807.92(a)(3)) that is not subject to Pre-market Approval. 21 C.F.R. § 807.81 provides, in part:

> § 807.81 When a premarket notification submission is required.
>
> (a) Except as provided in paragraph (b) of this section, each person who is required to register his establishment pursuant to § 807.20 must submit a premarket notification submission to the Food and Drug Administration at least 90 days before he proposes to begin the introduction or delivery for introduction into interstate commerce for commercial distribution of a device intended for human use which meets any of the following criteria:
>
> (1) The device is being introduced into commercial distribution for the first time ...
>
> ***
>
> (3) The device is one that the person currently has in commercial distribution or is reintroducing into commercial distribution, but that is about to be significantly changed or modified in design, components, method of manufacture, or intended use. The following constitute significant changes or modifications that require a premarket notification:

(i) A change or modification in the device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process.

The QSR and CGMP requirements

27. General regulatory provisions govern medical devices, such as the FDA's Quality System Regulations (QSR). 21 C.F.R. § 820.1(a)(1). The QSR sets out Current Good Manufacturing Practice (CGMP) requirements, which are "basic requirements" governing such things as "design, manufacture, packaging, [and] labeling" for all "finished medical devices." 21 C.F.R. § 820.1(a)(1).

28. The QSR sets out the requisite "framework that all manufacturers must follow" in establishing their own quality system procedures. These regulations "are intended to ensure that finished devices will be safe and effective . . . ."

29. Pursuant to federal regulations, including 21 C.F.R. § 820, the CGMPs mandate quality system compliance which, relevant to this case, include:

a. Manufacturers must meet quality standards in manufacturing and production; to include process validation, finished device acceptance activities, corrective and preventive actions (CAPA). In particular, each medical device manufacturer must put in place processes to test products for compliance with product specifications; to check and document compliance with product specifications before products are accepted for sale and use; and to identify and control nonconforming products. 21 C.F.R. §§ 820.72-820.90.
b. Manufacturers are required to use statistical techniques where necessary to evaluate product performance;
c. Manufacturers must establish and maintain procedures for implementing corrective actions and preventive actions;
d. Manufacturers must investigate the cause of nonconforming product and take corrective action to prevent recurrence;
e. Manufacturers are required to review and evaluate all complaints and determine whether an investigation is necessary.

30. The QSR has detailed corrective and preventive action (CAPA) requirements. These regulations include a provision that addresses a manufacturer's obligation to "establish and maintain procedures for implementing corrective and preventive action." 21 C.F.R. § 820.100(a). They also require manufacturers to "establish and maintain procedures" for "[i]nvestigating the cause of nonconformities relating to product, processes, and the quality system" and "[i]dentifying the action(s) needed to correct and prevent recurrence of nonconforming product and other quality problems." 21 C.F.R. § 820.100(a)(2)-(3).

Specific Provisions of QSR

31. The QSR regulation addressing nonconforming medical devices provides:

> § 820.90 Nonconforming product
>
> (a) Control of nonconforming product. Each manufacturer shall establish and maintain procedures to control product that does not conform to specified requirements. The procedures shall address the identification, documentation, evaluation, segregation, and disposition of nonconforming product. The evaluation of nonconformance shall include a determination of the need for an investigation and notification of the persons or organizations responsible for the nonconformance. The evaluation and any investigation shall be documented.
>
> (b) Nonconformity review and disposition.
> (1) Each manufacturer shall establish and maintain procedures that define the responsibility for review and the authority for the disposition of nonconforming product. The procedures shall set forth the review and disposition process. Disposition of nonconforming product shall be documented. Documentation shall include the justification for use of nonconforming product and the signature of

> the individual(s) authorizing the use.
>
> (2) Each manufacturer shall establish and maintain procedures for rework, to include retesting and reevaluation of the nonconforming product after rework, to ensure that the product meets its current approved specifications. Rework and reevaluation activities, including a determination of any adverse effect from the rework upon the product, shall be documented in the DHR.
> 21 C.F.R. § 820.90.

32. The QSR include specific requirements for manufacturer handling of complaints. They include:

> § 820.198 Complaint files.
>
> (a) Each manufacturer shall maintain complaint files. Each manufacturer shall establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit. Such procedures shall ensure that:
> (1) All complaints are processed in a uniform and timely manner.

33. A device is deemed adulterated if the methods used in, and the facilities and controls used for, its manufacture, packing, storage, and installation are not in conformity with CGMP requirements. A manufacturer's failure to comply with CGMPs applicable to a device renders the device adulterated under the FDCA 21 U.S.C. § 351(h); 21 C.F.R. Part 820.1(c). Each introduction of an adulterated device into interstate commerce is a violation of the FDCA. 21 U.S.C. § 331(a).

Changes Requiring Premarket Notification

34. Pursuant to 21 CFR § 807.81(a)(3), a manufacturer must submit a new premarket

notification (510(k)) to the FDA when:

> (3) The device is one that the person currently has in commercial distribution or is reintroducing into commercial distribution, but that is about to be significantly changed or modified in design, components, method of manufacture, or intended use. The following constitute significant changes or modifications that require a premarket notification:
>
> (i) A change or modification in the device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process.

In other words, a new 510(k) is required for a *significant change or modification* in the manufacturing process that could *significantly affect the safety or effectiveness* of the device.

35. The Draft Guidance: "510(k) Device Modifications: Deciding When to Submit a 510(k) for a Change to an Existing Device" (dated July 27, 2011) (hereinafter "510k Draft Guidance"), confirms the significance of changing performance characteristics or specifications, among other items:

> Device specifications include performance specifications (such as measurement accuracy), or physical or material characteristics (such as tensile strength). Changes to device specifications can significantly affect the performance of a device, and thus significantly affect a device's safety and effectiveness...

(P.8, 510k Draft Guidance)

> A new 510(k) submission should generally be submitted for modifications to device technology, engineering, and performance that significantly affect the cleared Indications for Use or fundamental technology of the existing device, or that substantially change the performance characteristics or specifications of the device.

(P.12, 510k Draft Guidance)

Device Reporting

36. Pursuant to federal regulations, manufacturers must report adverse events associated with a medical device to the FDA within 30 days after the manufacturer becomes aware that a device may have caused or contributed to serious injury, or that a device has malfunctioned and would be likely to cause or contribute to serious injury if the malfunction was to recur. Such reports must contain all information reasonably known to the manufacturer, including any information that can be obtained by analysis, testing, or other evaluation of the device, and any information in the manufacturer's possession. In addition, manufacturers are responsible for conducting an investigation of each adverse event, and must evaluate the cause of the adverse event. 21 C.F.R. Part 803.50.

37. Pursuant to federal regulations, manufacturer's must also describe in every individual adverse event report whether remedial action was taken in regard to the adverse event, and whether the remedial action was reported to the FDA as a removal or correction of the device. 21 C.F.R. Part 803.52.

38. Pursuant to federal regulations, manufacturers must report to the FDA within five (5) business days after becoming aware that a Medical Device Reporting (MDR) reportable event necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health. 21 C.F.R. Part 803.53. An MDR reportable event is, among other things, an event that makes a manufacturer aware that a device marketed by the manufacturer has malfunctioned or may have caused or contributed to a death or serious injury. 21 C.F.R. Part 803.3.

39. Similarly, device manufacturers must report promptly to the FDA any device corrections and removals, and maintain records of device corrections and removals. FDA regulations

require submission of a written report within ten working days of any correction or removal of a device initiated by the manufacturer to reduce a risk to health posed by the device, or to remedy a violation of federal law caused by the device that may present a risk to health. The written submission must contain, among other things, a description of the event giving rise to the information reported and the corrective or removal actions taken, and any illness or injuries that have occurred with use of the device, including reference to any device report numbers. Manufacturers must also indicate the total number of devices manufactured or distributed that are subject to the correction or removal, and provide a copy of all communications regarding the correction or removal. 21 C.F.R. Part 806.10.

40. Under federal regulations, a "[r]ecall means a firm's removal or correction of a marketed product that the Food and Drug Administration considers to be in violation of the laws it administers and against which the agency would initiate legal action, e.g., seizure." 21 C.F.R. Part 7.3(g).

DEVICE ALLEGATIONS

41. When Defendants turned a blind eye to FDA manufacturing and reporting requirements, they played a game of Russian roulette with patients' health, individual livelihoods, and liberty. These serious health risks become even more poignant when taking into account the fact that the vast majority of spending in Government Healthcare Programs is for elderly and disabled enrollees, who have extensive healthcare needs.

42. In addition, any patient that has been misdiagnosed due to a defective diagnostic device, is likely to, if they are lucky, require additional laboratory tests, physician visits, or invasive

procedure and medication, thereby additionally unnecessarily burdening Government Healthcare Programs; if they are unlucky, they will suffer severe injury or death.

43. In order to facilitate the continued reimbursement from Government Healthcare Programs, Defendants misrepresented and/or concealed material facts regarding their manufacturing methods, their finished products, and their adverse events.

44. Defendants completely disregarded their duty to deal honestly with the Government and with the knowledge that their silence would result in millions of dollars in damage to Government Healthcare Programs. Simply put, the products they produced, as described herein, were so defective and useless, rendering them neither useful, reasonable and necessary, or medically necessary for *any* patient.

Defective "Triage" Cardiovascular Panels and Triage TOX Drug Screen Panels Paid For By Government Healthcare Programs

45. The following devices were defective when utilized for tests on patients, yet the tests were reimbursed by Government Healthcare Programs. Defendants manufactured the devices with performance characteristics that were set below what was claimed as performance specifications in their respective product inserts (PI) and 510(k) submissions, rendering the diagnostic tests useless.

46. The devices released to the public, in turn, no longer resembled the devices approved/cleared in the 510 (k) submission or the package insert, relied upon by the FDA in its approval, and relied upon by healthcare providers in determining which devices to use for their patients.

The Triage Cardiovascular Panels

47. The Triage System includes the following: Diagnostic Devices and the Triage Meters. Diagnostic Devices are unit-use cartridges designed to perform specific diagnostic assays using patient samples. Triage Meters are portable fluorometers that read and interpret information from a Diagnostic Device and report the results in printed and electronic format.

48. At issue in this case are the "Diagnostic Devices"-these are the devices (a/k/a "panels" or "strips") upon which the blood or urine specimens are placed. If they are manufactured incorrectly, then they will be unreliable.

49. The five Triage cardiovascular panels are as follows:

Product Name	Markers/Assays	510K Summary	510K Decision Date
Triage Cardiac Panel	CKMB, Myoglobin, TNI	K030286	2/21/2003
Triage Cardiac profiler Panel	TNI, CKMB, Myoglobin, BNP	K030286	2/21/2003
Triage Profiler Shortness of Breath Panel	TNI, CKMB, Myoglobin, BNP, D-Dimer	K040437	6/25/2004
Triage BNP Test	BNP	K032235 K021317 K003475	1/28/2004 7/1/2002 11/13/2000
Triage D-Dimer Test	D-Dimer	K042890	11/29/2004

a. The Triage Cardiac Panel provides *"rapid, actionable information to aid in the diagnosis of acute myocardial infarction* [MI]." This diagnostic test is supposed to quantitatively detect elevations in certain blood chemistries (CK-MB, Myoglobin, and Troponin), permitting the rapid early diagnosis of a heart attack.

b. The Triage CardioProfilER Panel is a testing kit identical to the Triage Cardiac Panel, but the kit provides an additional test component B-type natriuretic peptide ("BNP"), which ostensibly assists in the diagnosis of "heart failure." BNP measures a decline in heart efficiency, or performance, which implies heart failure.

c. The Triage Profiler S.O.B. Panel is identical to the Triage CardioProfilER Panel, except for the inclusion of another test, the "D-Dimer." D-dimer is a blood test that assists in the diagnosis of deep vein thrombosis (DVT) and venous thromboembolism (VTE).

d. The Triage-BNP Panel contains only the test for BNP discussed above.

Defendants' Manufacturing Deficiencies

50. The methods for calculating the allowable degree of measurement variability in the Triage devices involve the statistical concepts of coefficients of variation ("CV") and confidence

intervals.

Improper Coefficients of Variation

51. The CV (computed as the standard deviation divided by the mean) is a statistical value which measures the spread of data around a given value (the mean), while taking into account the fact that variability increases as the measured value increases. The CV measures the extent to which multiple measurements tend to depart from their average value. The greater the CV, the less precise the measurement.

52. When it comes to diagnostic medical devices, the CV (characterized as precision/ imprecision in a 510(k) and PI) is of significant importance to the FDA. Indeed, in order to obtain the FDA's approval, medical device-makers must present all the clinical data obtained using devices of claimed precision/imprecision. In other words, the FDA approves a product because it believes the devices are safe and effective based on the data that was obtained using device lots with certain CV standard. Safety and effectiveness is not established for device lots that do not meet the CV standard.

53. Healthcare providers need to know the correct CV of a diagnostic device in order to properly interpret the data. The product insert tells providers what they should expect of the CV characteristic, for it tells them the precision of the product and reliability of the data. This greatly affects their decision of whether to use the product.

54. It is customary to test variation in devices at low, intermediate/medium, and high

concentrations of markers in test solutions, mimicking the situation with patients at various condition levels. Three calibration (testing) levels (including low, intermediate, and high Troponin I concentrations) span the entire range of clinically-likely patient presentations with no heart damage, to evolution of true, significant cardiac injury (from approximately 0.4 – 25.0 ng/ml). Each of these testing conditions generate results that are then subjected to statistical analysis for measurement of variation.

55. Defendant Alere SD's internal product release specifications for CVs were substantially higher than what was claimed in the product inserts and 510(k) summary documents. Alere SD arbitrarily excluded authentic test results so as to pass defective lots of its products through production, and out into interstate commerce, for use by Government Healthcare Program beneficiaries and others. The cherrypicking process of arbitrarily excluding evidence of variation internally was referred to as "trimmed mean."

56. When the CV of a device lot fails to meet the expected performance standard, the whole lot is substandard and fails. A manufacturer is obligated to rework until the devices meet the performance standard, or to scrap all the devices, thousands of them, each time a lot fails to meet the CV standard. Yet Defendants consistently failed to do so.

57. In addition to the high CVs, huge variability *between* lots occurred, as well. For example, Defendant Alere SD's internal final release Product-to-Product (P2P) specifications of Triage Cardiovascular devices have allowed 20%-45% (depending on markers) difference between the means of two lots when tested with the same sample.

58. Set forth below is a marker-by-marker comparison between the 510(k) summary, PI, and internal specifications at final release during 2010, and also pre-2010. Both show that the internal specifications allowed much higher CV's than the 510(k) summary or PI specifications.

CV comparison

Marker	510K summary (K040437)	Product Insert	%CV upper limit Final Release Spec. 2010 (trimmed mean method)	% CV upper limit Final Release Spec before 2010
BNP	109.1 pg/ml, CV (8.1 -8.1 %) 3432.74pg/ml CV(12.3-12.3pg/ml)	109.01 pg/ml, CV(8.1 -8.1%) 608.52 pg/ml, CV (9.8-10.0%) 3432.74pg/ml, CV (12.3-12.3%)	Cal H(low), CV 13,14,16% Cal E(Med), CV 17,17,20% Cal C(High), CV 17,17,20%	Cal H(low), CV16% Cal E(Med), CV,20% Cal C(High), CV 20%
CKMB	4.47 ng/ml, CV (11.2-12.2%) 18.66 ng/ml, CV (13.2 -14.3%)	4.47 ng/ml, CV (11.2 -12.2 %) 18.66ng/ml, CV (13.2-14.3%) 49.08ng/ml, CV(12.6 -12.5%)	Cal H(low), CV 15,16,18% Cal E(Med), CV 13,14,16% Cal C(High), CV 13,14,16%	Cal H(low), CV18% Cal E(Med), CV,16% Cal C(High), CV 16%
TNI	0.35 ng/ml, CV(11.7-12.3%) 11.6 ng/ml, CV (10.1 - 10.1%)	0.35 ng/ml, CV (11.7-12.3%) 1.22ng/ml, CV (11.7-12.3%) 11.60ng/ml, CV (10.1-10.1%)	Cal H(low), CV 14,15,17% Cal E(Med), CV 14,15,17% Cal C(High), CV 12,13,15%	Cal H(low), CV18% Cal E(Med), CV,15% Cal C(High), CV 15%
Myoglobin	78.93 ng/ml, CV(12.9-13.0%) 241.88ng/ml, CV(15.2-16.1%)	78.93 ng/ml, CV(12.9-13.0%) 122.52ng/ml, CV(13.5-14.5%) 241.88ng/ml, CV(15.2-16.1%)	Cal H(low), CV 13,14,16% Cal E(Med), CV 17,17,20% Cal C(High), CV 21,22,25%	Cal H(low), CV16% Cal E(Med), CV,20% Cal C(High), CV 25%
D-Dimer	128 ng/ml, CV(14.4-15.4%) 2990ng/ml, CV(6.0-6.1%)	128ng/ml, CV(14.4-15.4%) 451ng/ml, CV(9.7-10.7%) 2990ng/ml, CV(6.0-6.1%)	Cal H(low), CV 14,15,17% Cal E(Med), CV 12,13,15% Cal C(High), CV 12,13,15%	Cal H(low), CV17% Cal E(Med), CV,15% Cal C(High), CV 15%

Improper Confidence Levels

59. A confidence interval is an estimated range of values believed to contain an unknown parameter, the endpoints of which range reflect the confidence limits-which are defined by a stated probability that the unknown parameter is contained within the estimated range.

60. Defendants' internal specifications regarding confidence levels for each marker were significantly different than the PI or 510(k) submission levels, such that the difference drastically affected the safety and effectiveness of the devices. For instance, the product inserts and 510(k) summary documents for each of the multi-marker Triage products claimed 0.05 ng/ml detection limit of Troponin at 95% and 99% confidence level. Statistically, this means that less than 5% or 1% of blank sample data would reach level >0.05ng/ml. Despite this, Alere SD's internal specifications of final release allowed 15% of blank sample data to reach level >0.1 ng/ml. Clinically, a 0.05 ng/ml cut-off value is significant in medical decision making.

61. As a result of Defendants' watered-down internal product release specifications, Defendants released defective devices that, in each lot, produced a significant percentage of false positive results. Moreover, the internal specifications failed to measure false negative rates at all. This was occurring even though Defendants' marketing materials touted 100% accuracy for negative predictive value.

62. Set forth below are the specific differences between what Defendants represented in

their PI and 510(k) submission, versus its actual manufacturing practices, for each marker:

Detection limit

Marker	Detection limit with 95% confidence (stated on 510K summary and product insert)	Company Final Release specification (QTP-1694-14)
BNP	**5 pg/ml for BNP.** (510K K032235, K040437). Allow up to 5% of devices having BNP reading >5pg/ml when tested with zero Calibrator.	Allow 1 out of 10 devices (10%) having BNP reading >10pg/ml when tested with zero plasma sample. Allow 4 out of 26 devices (15.4%) having BNP reading >10pg/ml when tested with zero blood sample.
CKMB	**1.0ng/ml for CKMB** (510K K040437). Allow up to 5% devices having CKMB reading >1.0ng/ml when tested with zero Calibrator.	Allow 1 out of 10 devices (10%) having CKMB reading >2.0ng/ml when tested with zero plasma sample. Allow 4 out of 26 devices (15.4%) having CKMB reading >2.0ng/ml when tested with zero blood sample.
TNI	**0.05ng/ml for TNI**. (510K K040437). Allow up to 5% devices having TNI reading >0.05ng/ml when tested with zero Calibrator.	Allow 1 out of 10 devices (10%) having TNI reading >0.1ng/ml when tested with zero plasma sample. Allow 4 out of 26 devices (15.4%) having TNI reading >0.1ng/ml when tested with zero blood sample.
Myoglobin	**5ng/ml for Myoglobin**. (510K K040437). Allow up to 5% devices having Myoglobin reading >5ng/ml when tested with zero Calibrator.	Allow 1 out of 10 devices (10%) having Myoglobin reading >10ng/ml when tested with zero plasma sample. Allow 4 out of 26 devices (15.4%) having Myoglobin reading >10ng/ml when tested with zero blood sample.
D-Dimer	**100ng/ml for D-Dimer**. (510K K040437). Allow up to 5% devices having D-Dimer reading >100ng/ml when tested with zero Calibrator.	Allow 1 out of 10 devices (10%) having D-Dimer reading >200ng/ml when tested with zero plasma sample. Allow 4 out of 26 devices (15.4%) having D-Dimer reading >200ng/ml when tested with zero blood sample.

Non-Disclosed Myo Hook Problem

63. Blood myoglobin concentrations can become highly increased in some patients when tested. A myoglobin "hook effect" occurs when falsely low values occur on an immunoassay when an overwhelming amount of antigen affects the binding capacity of the added antibody. In the case of a high concentration of myoglobin on a specimen, a myo hook phenomenon occurs when the result is falsely low because of the hook phenomenon at high concentrations.

64. Defendants have failed to eliminate or disclose the myo hook issue, and therefore physicians have had no idea of the possibility of a high-dose hook effect in the myoglobin marker in the subject Triage products. During manufacturing, Defendants' internal specifications allowed a myo hook in up to one out of ten devices.

The Triage TOX Drug Screen Panels

65. This drug screen is a immunoassay (intended to be used with the Triage Meters) which purportedly determines the presence of common drugs of abuse based upon urine specimens; 90-100% of them are defective. There are three versions of TOX, with the more recent generally replacing the older versions:

Product Name	Markers/Assays	510K Summary	510K decision date
Triage TOX drug screen	AMP, mAMP, BAR, BZO, COC, OPI, PCP, THC, TCA	K012745	1/10/2002
Triage TOX drug screen (+APAP)	Same as above plus APAP	K043242	2/28/2005
Triage TOX drug screen (+MTD)	Same as above plus APAP and MTD	K060791	6/22/2006

66. Page 13 of the PI provides accuracy specifications as follows:

50% Below Threshold

	APAP	AMP	mAMP	BAR	BZO	COC	MTD	OPI	PCP	THC	TCA
Concentration	2.5	500	500	150	150	150	150	150	12.5	25	500
Positive/Negative	0/10	0/10	0/10	0/10	0/10	0/10	0/10	0/10	0/10	0/10	0/10
Accuracy	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%

25% Below Threshold

	APAP	AMP	mAMP	BAR	BZO	COC	MTD	OPI	PCP	THC	TCA
Concentration	3.75	750	750	225	225	225	225	225	18.75	37.5	750
Positive/Negative	4/26	0/30	0/30	1/29	0/30	1/29	0/30	0/30	1/29	0/30	0/30
Accuracy	87%	100%	100%	97%	100%	97%	100%	100%	97%	100%	100%

50% Above Threshold

	APAP	AMP	mAMP	BAR	BZO	COC	MTD	OPI	PCP	THC	TCA
Concentration	7.5	1500	1500	450	450	450	450	450	37.5	75	1500
Positive/Negative	10/0	10/0	10/0	10/0	10/0	10/0	10/0	10/0	10/0	10/0	10/0
Accuracy	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%

25% Above Threshold

	APAP	AMP	mAMP	BAR	BZO	COC	MTD	OPI	PCP	THC	TCA
Concentration	6.25	1250	1250	375	375	375	375	375	31.25	62.5	1250
Positive/Negative	28/2	30/0	29/1	28/2	30/0	29/1	28/2	25/5	27/3	30/0	28/2
Accuracy	93%	100%	97%	93%	100%	97%	93%	83%	90%	100%	93%

67. Nearly all of the lots were defective. This is because Defendants' internal final release specifications for accuracy were as follows:

Final Release specification for accuracy

50% below Threshold

	APAP	AMP	mAMP	BAR	BZO	COC	MTD	OPI	PCP	THC	TCA
Concentration (ng/ml)	2.5	500	500	150	150	150	150	150	12.5	25	500
Pos/Neg	No spec.	No spec.	No spec.	No spec.	No spec.	No spec.	No spec.	No spec.	No spec.	3/17	No spec.
Accuracy	No spec.	No spec.	No spec.	No spec.	No spec.	No spec.	No spec.	No spec.	No spec.	85%	No spec.

25% below Threshold

	APAP	AMP	mAMP	BAR	BZO	COC	MTD	OPI	PCP	THC	TCA
Concentration (ng/ml)	3.75	750	750	225	225	225	225	225	18.75	37.5	750
Pos/Neg	No spec.	No spec.	No spec.	No spec.	No spec.	No spec.	No spec.	No spec.	No spec.	No spec.	No spec.
Accuracy	No spec.	No spec.	No spec.	No spec.	No spec.	No spec.	No spec.	No spec.	No spec.	No spec.	No spec.

25% above Threshold

	APAP	AMP	mAMP	BAR	BZO	COC	MTD	OPI	PCP	THC	TCA
Concentration (ng/ml)	6.25	1250	1250	375	375	375	375	375	31.25	62.5	1250
Pos/Neg	No spec.	No spec.	No spec.	No spec.	No spec.	No spec.	No spec.	No spec.	No spec.	No spec.	No spec.
Accuracy	No spec.	No spec.	No spec.	No spec.	No spec.	No spec.	No spec.	No spec.	No spec.	No spec.	No spec.

50% above Threshold

	APAP	AMP	mAMP	BAR	BZO	COC	MTD	OPI	PCP	THC	TCA
Concentration (ng/ml)	7.5	1500	1500	450	450	450	450	450	37.5	75	1500
Pos/Neg	No spec.	No spec.	No spec.	No spec.	No spec.	No spec.	No spec.	No spec.	No spec.	No spec.	No spec.
Accuracy	No spec.	No spec.	No spec.	No spec.	No spec.	No spec.	No spec.	No spec.	No spec.	No spec.	No spec.

150% above Threshold

	APAP	AMP	mAMP	BAR	BZO	COC	MTD	OPI	PCP	THC	TCA
Concentration (ng/ml)	12.5	2500	2500	750	750	750	750	750	62.5	125	2500
Pos/Neg	23/3	23/3	23/3	23/3	23/3	23/3	23/3	23/3	23/3	23/3	23/3
Accuracy	88%	88%	88%	88%	88%	88%	88%	88%	88%	88%	88%

Drug free urine

	APAP	AMP	mAMP	BAR	BZO	COC	MTD	OPI	PCP	THC	TCA
Concentration (ng/ml)	0	0	0	0	0	0	0	0	0	0	0
Pos/Neg	3/23	3/23	3/23	3/23	3/23	3/23	3/23	3/23	3/23	3/23	3/23
Accuracy	88%	88%	88%	88%	88%	88%	88%	88%	88%	88%	88%

68. Moreover, Defendants weakened their quality control practices by removing crucial quality check steps, including an Error Code Investigation. For instance, if a TOX device lot had more than two error codes observed during calibration testing, additional tests should have been performed to determine the root cause of the error codes. Defendants refused to do this.

Defendants' Knowledge

69. Defendants' Design Input Requirements (DIRs) for reliability, the specific metrics that manufacturers design their products to meet, may have been *unreliable* from the outset. Defendants' internal documentation shows graphs appearing to show that Defendants actually designed the cardiac devices to allow for higher CV's than submitted with their 510(k)'s. For example, it appears that the BNP product was designed to have a CV of 16%. This would mean that Defendants' BNP 510(k) contained an intentionally fabricated CV of 12%, vastly more reliable than the true capabilities of the product.

70. Defendants manufactured the subject products outside of their FDA approved/cleared specifications, because if they rejected products that did not meet the specifications, their manufacturing yields would have been minimal. Thus, Defendants lowered their specifications thresholds and ordered employees to follow such revised specifications, even though they were in violation of their FDA-approved/cleared specifications submitted with their 510 (k)'s, they were in violation of federal laws and regulations, and did so in the face of thousands of complaints about their faulty devices.

71. Defendants were aware that the devices did not meet the 510(k) and PI specifications.

Defendants knew that it would cost millions of dollars to actually follow the specifications they had represented to the FDA in their 510 (k)'s and their PI's.

72. Defendants were aware that their manufacturing processes were deficient.

a. An April 22, 2004 email from a Process Analyst to then Vice President of Operations, reports back that "in April and March, all of the BNPs passed initial testing for CV specification at 17%, with the exception of one lot," which lot ultimately passed after it was "retested" and "outliers were removed."

b. In a June 24, 2005 email and accompanying May 2005 Internal Quality Audit Report, in the Executive Summary provides: "[T]here are elements of the Production and Process Controls, which are not in placed [sic], clearly defined or implemented. Most of the observations are classified as major."

c. In a December 20, 2005 email to the Senior Director of Manufacturing, one Senior Process Analyst wrote:

> From the data that I see day to day, it is easy to conclude our inserts are misleading. Take MYO for example, it is highly doubtful that repeating the same procedure as stated in the insert would yield a MYO CV close to the within day 10.8% CV at the high end as stated in the PI. Just look at our current data:
>
> Furthermore, it is disconcerting that we still release lots that are marginal to internal specifications, when these internal specifications are more lenient and more distant from our insert claims (from the above example, MYO spec is <=25%).

d. In a 2006 email to the Director of Research & Development and others, an Analyst pushed senior management to change their fraudulent ways. Notably, she raised serious concerns that the "final CV data that [they] release lots with are not necessarily real" and that they were "fudging" their numbers. Quantifying the true scope of the deception, she noted, "[O]ur accuracy limit [for TOX production] would be around 55-60% which is far off from data published on our inserts (accuracy: 97%-100% using 0.75X and 87%-100% using 1.25X)."

73. These concerns were also captured in an internal document that listed the "top few performance characteristics that most customers in the field would like to see improved." Stated concerns included the following:

- Our internal specifications should be harmonized with the Package Insert (PI) ranges (for example, MYO PI at high end = 10.8% vs. calibration specification of <25%).
- Precision of the products across the entire diagnostic range should reflect the values stated in the PI.
- BNP precision is a major issue. Although Biosite is not approved for using BNP for time progression analysis but have investigational papers supporting it, customers may still use BNP devices to monitor the progress of a patient after treatment. That is, patients' samples are run at several time points.
    - The problem comes up with precision. If BNP results go from 1000 to say 700 on two different time points is the patient getting better with treatment or is this just a reflection of our imprecision (for example, a 2sd range with 15% Cvs).
    - It is believed that if we can get approved for time progression diagnosis for BNP, that we would have a lot more sales. This increase in sales, however, has not been quantified or is not thoroughly analyzed.

Failure to Report Adverse Events

74. The FDA maintains a publicly-accessible database, called the "Manufacturers and User Facility Device Experience Database" or "MAUDE" database, which lists adverse events reported by users of medical devices.

75. Since at least 2003, Defendants have tracked customer complaints, on a week-by-week basis, tallying the mounting concerns about the inaccuracy of their devices.

76. Defendants have suppressed and failed to report adverse events for their products, as required by federal law. For instance, there were only four MAUDE Adverse Event Reports for Triage TOX panel found in the MAUDE FDA database for the last 10 years. However, Defendants' internal report showed that 346 complaints concerning THC assay (one of eleven assays on TOX panel) were submitted to Alere SD in 2010 alone.

Material Allegations

77. Each of the products at issue are devices, as that term is defined in Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 321(h), because they are intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, or is intended to affect the structure of function of the body. FDA cleared each device under Premarket Notification Submission (510(k)).

78. Having had their products cleared by 510(k) approval, Defendants were

required to comply with both the device-specific requirements set forth in their 510(k) applications and approvals, as well as the general federal safety regulations governing all medical devices. These include, but are not limited to, the federal QSR and CGMP regulations.

79. Defendants failed to comply with federal regulations, including, but not limited to, 21 C.F.R. § 803, which requires device manufacturers to report deaths and serious injuries that a device may have caused or contributed to causing; Section 806, which requires device manufacturers to report device corrections; Section 807 which requires device manufacturers to make premarket notification submissions to the FDA; and Section 820, which requires device manufacturers to comply with the CGMP requirements.

80. Violations of Section 820 include, but are not limited to: (1) "Failure to establish and maintain procedures for identifying all of the actions needed to correct and prevent the recurrence of nonconforming product and other quality problems, and verifying or validating the corrective and preventive action to ensure that such action is effective as required by 21 CFR § 820.100(a)(3) & (a)(4)," (2) "Failure to establish and maintain procedures for monitoring and control of process parameters for validated processes to ensure that the specified requirements continue to be met as required by 21 CFR § 820.75(b)."

81. Violations of Section 807.81, which provides that a premarket notification submission is required when an existing device with 510(k) clearance device is being marketed and is to be changed or modified in a way that could significantly affect its safety or effectiveness, include that Defendants changed the internal performance specifications of each device - such that the performance characteristics of the devices, as listed in device labeling or in finished product

release specifications, no longer resembled the device performance characteristics being released into interstate commerce, including but not limited to the measurement accuracy of each device. Defendants further changed the design materials, chemical composition, method of manufacturing, etc., which also required submission of a new premarket notification (510K) to the FDA.

82. Defendants violated federal law in the following ways:

a. Deviating from the FDA-cleared design and manufacturing specifications for their devices;
b. Failing to obtain supplemental FDA approval for their changes to the manufacturing and specifications of their devices that could affect the safety and effectiveness of a device;
c. Failing to comply with applicable CGMPs in the manufacture of its devices;
d. Failing to comply with applicable adverse event reporting requirements.

83. Defendants expressly, impliedly, falsely and fraudulently represented to the FDA that their devices were in compliance with federal law and regulations, not adulterated, and safe and effective for the use for which they were intended.

84. Defendants were aware that the devices had defects that could potentially and likely cause injury and death to users of the devices since they were prone to inaccuracy, false positives and negatives. This, in turn, they knew would increase costs to Government Healthcare Programs.

85. At all relevant times to this action, Defendants knew, based on internal specifications, complaints of their users, internal and external audits, and other information, that the devices were defectively manufactured, adulterated, and in violation of federal safety regulations and laws, and were not made resembling the characteristics set forth in their respective package inserts and 510(k)'s.

86. Despite the actual knowledge described herein above, Defendants intentionally fabricated and/or suppressed their internal findings, their manufacturing processes and other information required by federal law to be maintained by it as a part of its CGMP requirements and/or submitted to the FDA.

87. Defendants' failure to meet the above-referenced federal requirements applicable to medical devices and Defendants' other acts and omissions as described, are in violation of federal law, rendering the devices adulterated, unfit for sale, defective, and non-covered under the Government Healthcare Programs. The devices were non-covered because they caused them to be further variable and therefore, were defective, not "reasonable and necessary," and/or required a new premarket notification.

88. Defendants caused third parties to submit false claims to Government Healthcare Programs, as they caused providers to submit claims based on wholly defective diagnostic tests. The Medicare Act authorizes payment for "medical and other health services," including "diagnostic laboratory tests," but only if such services are "reasonable and necessary for the diagnosis of treatment or illness." 1395y(a)(1)(A). The other Government Healthcare Programs require the same or similar reasonable and necessary standards. The CPT codes on which the false claims were based are:

Test Name	CPT® Code[1]	CPT Code Description
BNP	83880 - QW	NATRIURETIC PEPTIDE
D-dimer	85379	FIBRIN DEGRADATION PRODUCTS, D-DIMER; QUANTITATIVE
Cardiac Panel	82553	CREATINE KINASE (CK), (CPK); MB FRACTION ONLY
	83874	MYOGLOBIN
	84484	TROPONIN, QUANTITATIVE
CardioProfilER® Panel	83880	NATRIURETIC PEPTIDE
	82553	CREATINE KINASE (CK), (CPK); MB FRACTION ONLY
	83874	MYOGLOBIN
	84484	TROPONIN, QUANTITATIVE
Profiler SOB™ (Shortness of Breath) Panel	83880	NATRIURETIC PEPTIDE
	82553	CREATINE KINASE (CK), (CPK); MB FRACTION ONLY
	85379	FIBRIN DEGRADATION PRODUCTS, D-DIMER; QUANTITATIVE
	83874	MYOGLOBIN
	84484	TROPONIN, QUANTITATIVE
TOX Drug Screen	G0434	DRUG SCREEN, OTHER THAN CHROMATOGRAPHIC; ANY NUMBER OF DRUG CLASSES, BY CLIA WAIVED TEST OR MODERATE COMPLEXITY TEST, PER PATIENT ENCOUNTER

COUNT I
FALSE CLAIMS ACT
31 U.S.C. § 3729(a)(1)/3729(a)(1)(A)

89. Relator realleges and incorporates by reference paragraphs 1 through 88 as though fully set forth herein.

90. This is a claim by Relator, on behalf of the United States, for treble damages and penalties under the FCA, 31 U.S.C. § 3729-3733 against Defendants for knowingly causing to be presented false claims to Government Healthcare Programs. Defendants have knowingly and

willfully caused to be presented false claims as described in this Complaint.

91. Defendants have knowingly caused the use of its defective diagnostic tests throughout the United States, knowing that the claims for the diagnostic tests would be submitted to Government Healthcare Programs for reimbursement.

92. By virtue of the false claims caused to be presented by Defendants, the United States is entitled to three times the amount by which it was damaged, to be determined at trial, plus a civil penalty of not less than $5,500.00 and not more than $11,000.00 for each false claim presented or caused to be presented.

COUNT II
FALSE CLAIMS ACT
31 U.S.C. §§ 3729(a)(2)/3729(a)(1)(B) (CGMP)

93. Relator realleges and incorporates by reference paragraphs 1 through 88 as though fully set forth herein.

94. Defendants have used a variety of false documents, including false submissions to the United States FDA, to cause the United States to continue to pay and approve claims for reimbursement under the Government Healthcare Programs, which claims would not have been reimbursed had CMS known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of the Defendants' products described in this Complaint.

95. From in or about 1999 to present, Defendants' conduct violated the False Claims Act, 31 U.S.C. §§ 3729(a)(2) and its successor provision, 31 U.S.C. §§ 3729(a)(1)(B).

96. The United States is entitled to three times the amount by which it was damaged, to be determined at trial, plus a civil penalty of not less than $5,500.00 and not more than $11,000.00 for each false claim paid or approved.

COUNT III
MARYLAND FALSE HEALTH CLAIMS ACT OF 2010

97. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 88 above as if fully set forth herein.

98. This is a *qui tam* action brought by Relator on behalf of the State of Maryland to recover treble damages and civil penalties under the Md. Health General Code Subtitle 6 §§ 2-601 *et seq*.

99. Defendants violated Md. Health General Code Subtitle 6 § 2-602, which provides in pertinent part:

> (a) A person may not:
> (1) Knowingly present or cause to be presented a false or fraudulent claim for payment or approval;
> (2) Knowingly make, use, or cause to be made or used a false record or statement material to a false or fraudulent claim ...
> ***
> (9) Knowingly make any other false or fraudulent claim against a State health plan or a State health program.

100. The State of Maryland, by and through the Maryland Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

101. Compliance with applicable Medicare, Medicaid and the various federal laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Maryland in connection with Defendants' conduct. Compliance with applicable Maryland statutes and regulations was also an express condition of payment of claims submitted to the State of Maryland.

102. As a result of Defendants' violation of Md. Health General Code Subtitle 6 § 2-602 *et seq.*, the State of Maryland has been damaged.

103. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Md. Health General Code Subtitle 6 § 2-602 *et seq.* on behalf of herself and the State of Maryland.

104. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Maryland in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the State of Maryland:

(1) Three times the amount of damages that the State of Maryland sustains as a result of Defendants' conduct;
(2) A civil penalty of not more than $10,000 for each false claim which Defendants caused to be presented to the State Maryland;
(3) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to Md. Health General Code Subtitle 6 § 2-602 *et seq.* and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT IV
31 U.S.C. § 3730(h)

105. Relator realleges and incorporates by reference the allegations made in paragraphs 1 through 88 of this Complaint.

106. Alere San Diego and Alere, Inc. have a duty under the False Claims Act, 31 U.S.C. § 3730(h), to refrain from taking retaliatory actions against employees who take lawful actions in furtherance of a False Claims Act action, or who take action to stop one or more violations of the False Claims Act.

107. Relator took lawful actions to stop one or more violations of the False Claims Act, and in furtherance of a False Claims Act action, including, but not limited to, investigation for, testimony for, or assistance in an action filed under this section and, as such, engaged in protected activity under the False Claims Act and other laws.

108. Beginning in or about December 2009 and continuing thereafter, Alere San Diego and Alere, Inc. discharged, threatened, harassed and/or discriminated against Relator, in the terms and conditions of her employment, which included and was not limited to the following:

a. In December 2009, Relator raised concerns to Lauren Dale-Dolphin, Alere San Diego's Quality Control Manager, regarding the release of TOX products that showed a high

potential of false positives. Relator's efforts to safeguard the quality of TOX products were branded, by Dale-Dolphin, as emotional arguments without data support. From that point forward, it became increasingly more difficult for Relator to request retests for the lots in which she saw potential quality issues.

b. In June 2010, Lauren Dale-Dolphin started an initiative to replace real-time stability studies with accelerated stability strides for product post market surveillance monitoring. The Relator fought hard against this initiative, as she felt the real-time stability studies kept the stability study program in compliance.

c. On or about March 2 - 4, 2011, Lauren Dale-Dolphin asked the Relator to use failed device lots on a real-time stability study in support of product shelf life claims. Relator objected to this request and did not follow through on it because of the high likelihood of tainted stability results.

d. On or about March 3 - 4, 2011, Lauren Dale-Dolphin was advised by the Relator of quality control issues on a TOX lot, along with an email stating she wanted to retest the lot. Dale-Dolphin balked and pushed the Relator to sign-off on and release the TOX lot anyway, even though there were potential quality issues. Dale-Dolphin called for a vote from Relator's TOX team colleagues and unexpectedly met resistance from all involved and was not able to release the lot without a retest. Dale-Dolphin became highly critical of Relator's work and created obstacles to make the retest more difficult. Relator believes this most recent criticism would not have occurred had she simply released the lot upon Dale-Dolphin's request.

e. On or about March 7, 2011, Relator was given a negative performance review and handed a performance improvement plan (PIP) despite the fact that Relator was nominated and

awarded three Company Star Awards recognizing her good work and contributions in 2009 and 2010.

f. On or about April 1, 2011, Relator was summoned to Lauren Dale-Dolphin's office. Dale-Dolphin said she wanted to announce to the Relator her merit increase. After Relator sat down for the meeting, Dale-Dolphin proudly advised that her increase would be 0% (the average raise was 4% companywide); that is what she proposed and the company agreed with her. This was despite the fact that during the applicable ratings period, Relator devised a change to cardiac problematic lots saving them from scrapping, resulting in a savings of over $1.2 million to the Defendants.

g. On April 6, 2011, Relator met with Dave Streich, Vice President of Human Resources in his office. Relator had submitted to the company a written complaint dated March 5, 2011, and subsequently orally chronicled additional problems with the testing of the lots and stability studies. Relator expressed her frustration at the meeting that while Defendants' code of business conduct guided her in reporting quality issues without worrying about retaliation, she felt that the company was not hearing her voice. Streich said that the investigation was done, the review was fair, and Relator's complaints were not meritous. Streich further advised Relator that the Performance Improvement Plan was what the company wanted the Relator to do, and that if Relator did not complete the items on the PIP, she needed to find something else to make a living.

h. On April 15, 2011, the new VP of Manufacturing, Michael Imrich, sent out an email that he was comfortable with the data and wanted to release some TOX lots held up by (Relator) due to PCP false positive issues. Ms. Dale-Dolphin forwarded Relator the email and asked her to release them. Relator told her there as another TOX lot with similar issues that was not listed on the email.

Dale-Dolphin asked Relator to write an email to the people saying that Relator recommended releasing the lot. Relator agreed to send out an email but did not agree to recommend releasing the products. Dale-Dolphin was furious with Relator.

i. On April 19, 2011, batch records came to Relator's desk for final review to scrap Tox Lot W48872. In the process of reviewing these batch records, Relator discovered that a false calibration report was created by a Process Analyst (as requested by Dale-Dolphin) to make it look like those defective devices with error codes were caught by the release specifications. The purpose of doing that was to hide the fact that defective devices can be released with the Defendants' more lenient release specifications. Since the error code investigation step was already removed from internal procedures, and analysts were reminded not to do error code investigation, this kind of defective device lot would not be caught in the future. Relator refused to sign-off on the false report and wanted to reinstate the error code investigation.

j. On April 19, 2011, the Human Resources Business Manager and Lauren Dale-Dolphin met with Relator in Dale-Dolphin's office. Several documents were on her desk for Relator to sign, including a Final Written Warning and a Revised Performance Work Plan. Relator saw the paperwork, felt that they were outrageous, and refused to sign them. Relator was asked to leave the company premises immediately.

k. On April 21, 2011, the Human Resources Business Manager advised Relator that Defendants' management had made the determination to terminate her, but would offer a severance package. Relator took her personal items out of her desk and was escorted in and out of the building.

109. Relator was discriminated against in the terms and conditions of her employment by Alere San Diego and Alere, Inc., by and through its officers, agents, and employees because of lawful acts done by her in the furtherance of her efforts to bring a False Claims Act action and to stop one or more violations of the False Claims Act.

110. The actions of Alere San Diego and Alere, Inc. damaged and will continue to damage Relator in violation of 31 U.S.C. § 3730(h), in an amount to be determined at trial.

111. Pursuant to 31 U.S.C. § 3730(h), Relator is entitled to back pay, special damages, as well as litigation costs and reasonable attorneys' fees incurred in the vindication of her reputation and the pursuit of her retaliation claims.

COUNT V
Cal. Gov. Code § 12653 (b)

112. Relator realleges and hereby incorporates by reference each and every allegation contained in paragraphs 1 through 88 and paragraphs 105 through 131, of this complaint.

113. During her employment with Alere San Diego and Alere, Inc., Relator lawfully investigated failures of Alere San Diego and Alere, Inc. to comply with the State of California and Federal False Claims Acts in furtherance of False Claims Act actions. She complained to her superiors regarding the violations set forth in this Complaint.

114. Relator's actions in furthering a False Claims Act action and internally reporting Alere San Diego and Alere, Inc.'s violations of laws were protected activities within the meaning of Cal. Gov. Code § 12653(b).

115. Alere San Diego and Alere, Inc. were aware of the Relator's above complaints and reports, and the potential effect of same on receiving federal and state funds.

116. Relator's complaints put Alere San Diego and Alere, Inc. on notice that Relator's complaints could lead to an action filed or to be filed under Section 12652.

117. In retaliation for investigating and reporting said violations, Alere San Diego and Alere, Inc. harassed, threatened, discriminated and ultimately discharged Relator in or about April 21, 2011.

118. Alere San Diego and Alere, Inc.'s actions were in violation of Cal. Gov. Code § 12653(b), and damaged Relator in violation of Cal. Gov. Code § 12653(b), in an amount to be determined at trial.

119. Pursuant to Cal. Gov. Code § 12653(c), Relator is entitled to reinstatement with seniority, two times the amount of back pay owed, interest on back pay, compensation for any special damages sustained as a result of the discriminatory treatment, litigation costs, and reasonable attorney's fees incurred in the vindication of her reputation and in pursuit of this retaliation claim.

120. As a direct and proximate result of Alere San Diego and Alere, Inc.'s conduct as alleged herein, Relator has suffered damage to her reputation entitling Relator to general damages in an amount to be determined at trial.

121. Alere San Diego and Alere, Inc.'s conduct as alleged above in harassing and ultimately, constructively terminating Relator, was willful, malicious, oppressive, and fraudulent, thereby entitling Relator to punitive damages.

COUNT VI
Retaliation - Public Policy

122. The allegations set forth in paragraphs 1 through 88, and paragraphs 105 through 131, are alleged and incorporated herein by reference.

123. Defendant Alere San Diego and Alere, Inc. has retaliated against Relator in violation of California public policy, by engaging in a course of retaliatory conduct. This conduct continued until Relator was terminated and discharged in or about April 21, 2011. Relator believes and alleges that Alere San Diego and Alere, Inc.'s termination of her employment and discharge contravenes fundamental public policy established both by statutory and regulatory provisions, in violation of California public policy.

124. At all times mentioned herein, Relator was willing and able to perform the duties and functions of her position and Relator did, in fact, perform those duties in an excellent fashion.

125. As a proximate result of Alere San Diego and Alere, Inc.'s discriminatory actions against Relator as alleged above, Relator has been harmed in that Relator has suffered the loss of salary, benefits, and additional amounts of monies she would have received if Alere San Diego and Alere, Inc. had not terminated her employment. As a result of such discrimination and consequent harm, Relator has suffered such damages in an amount according to proof.

126. As a further proximate result of Alere San Diego and Alere, Inc.'s discriminatory actions against Relator as alleged above, Relator has been harmed in that she has suffered humiliation, anguish, and emotional and physical distress. As a result of such discrimination and consequent harm, Relator has suffered such damages in an amount according to proof.

127. The above-recited actions of Alere San Diego and Alere, Inc. were done with malice, fraud, and/or oppression, and in reckless disregard of Relator's rights entitling Relator to an award of punitive damages.

COUNT VII
Retaliation - California Health and Safety Code Section 1278.5:

128. Relator realleges and incorporates by reference the allegations made in Paragraphs 1 through 88, and paragraphs 105 through 131 of this Complaint.

129. California Health and Safety Code Section 1278.5(b)(1) provides that "No health facility shall discriminate or retaliate, in any manner, against any patient, employee, member of the medical staff, or any other health care worker of the health facility because that person has done either of the following: (a) Presented a grievance, complaint, or report to the facility, to an entity or agency responsible for accrediting or evaluating the facility, or the medical staff of the facility, or to any other governmental entity.

130. Relator made complaints to Alere San Diego and Alere, Inc. about violations of the False Claims Act and patient safety concerns. Within 120 days of the complaints and reporting, Alere San Diego and Alere, Inc. discriminated against Relator Wu. Alere San Diego and Alere, Inc. harassed and/or discriminated against Relator in the terms and conditions of employment, ultimately terminating and discharging her in or about April 21, 2011.

131. Alere San Diego and Alere, Inc.'s actions damaged Relator in violation of § 1278.5(b)(1) in an amount to be determined at trial.

WHEREFORE, as to Counts I through VII, plaintiff/relator requests that judgment be entered against Defendants as follows:

a. Defendants pay an amount equal to three times the amount of damages the United States have sustained because of Defendants' actions, plus a civil penalty against Defendants of not less than $5,500, and not more than $11,000 for each violation of 31 U.S.C. § 3729;

b. plaintiff/relator be awarded the maximum amount allowed pursuant to 31 U.S.C. § 3730(d);

c. plaintiff/relator be awarded all costs of this action, including attorneys' fees, expenses, and costs pursuant to 31 U.S.C. § 3730(d) and (h) and California law;

d. plaintiff/relator be awarded appropriate money damages and interest for unlawful discharge including, but not limited to, compensatory damages for harm, humiliation, embarrassment, and mental anguish and punitive damages for Alere San Diego and Alere, Inc.'s conduct and the conduct of officers, agents, and employees of Defendant in violation of 31 U.S.C. § 3730 and/or California law;

e. the United States and plaintiff/relator be granted all such other relief as the Court deems just and proper.

COUNT VIII
CALIFORNIA FALSE CLAIMS ACT

132. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 88 above as if fully set forth herein.

133. This is a *qui tam* action brought by Relator on behalf of the State of California to recover treble damages and civil penalties under the California False Claims Act, Cal. Gov't. Code § 12650 *et seq.*

134. Defendants violated Cal. Gov't Code § 12651(a), which provides liability for any person who:

> (1) knowingly presents, or causes to be presented, to an officer or employee of the state or of any political division thereof, a false claim for payment or approval;
> (2) knowingly makes, uses, or causes to be made or used a false record or statement to get a false claim paid or approved by the state or by any political subdivision;
> (3) conspires to defraud the state or any political subdivision by getting a false claim allowed or paid by the state or by any political subdivision.
> ...
> (8) is a beneficiary of an inadvertent submission of a false claim to the state or a political subdivision, subsequently discovers the falsity of the claim, and fails to disclose the false claim to the state or the political subdivision within a reasonable time after discovery of the false claim.

135. The State of California, by and through the California Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

136. Compliance with applicable Medicare, Medi-Cal and the various federal laws cited herein was an implied, and upon information and belief; also an express condition of payment of claims submitted to the State of California in connection with Defendants' conduct. Compliance with applicable California statutes and regulations was also an express condition of payment of claims submitted to the State of California.

137. As a result of Defendants' violation of Cal. Gov't Code § 12651(a), the State of California has been damaged.

138. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Cal. Gov't Code § 12652(c) on behalf of herself and the State of California.

139. This Court is requested to accept pendant jurisdiction over this related state claim as it is predicated upon the same exact facts as the federal claim, and merely asserts separate damages to the State of California in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the State of California:

(1) Three times the amount of actual damages which the State of California has sustained as a result of Defendants' conduct;
(2) A civil penalty of up to $10,000 for each false claim which Defendants presented or caused to be presented to the State of California;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to Cal. Gov't Code § 12652 and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT IX
COLORADO MEDICAL ASSISTANCE ACT

140. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 88 above as if fully set forth herein.

141. This is a *qui tam* action brought by Relator on behalf of the State of Colorado to recover treble damages and civil penalties under the Colorado Medical Assistance Act, Colo. Rev. Stat. §§ 25.5-4-304 *et seq*.

142. Defendants violated Colo. Rev. Stat § 25.5-4-305, which provides that it is unlawful to:

(a) Intentionally or with reckless disregard make or cause to be made any false representation of a material fact in connection with a claim;

(b) Intentionally or with reckless disregard present or cause to be presented to the state department a false claim for payment or approval;

(c) Intentionally or with reckless disregard present or cause to be presented any cost document required by the medical assistance program that the person knows contains a false material statement…

143. The State of Colorado, by and through the Colorado Medical Assistance Act and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

144. Compliance with applicable Medicare, Medicaid and the various federal laws cited herein was an implied, and upon information and belief; also an express condition of payment of claims submitted to the State of Colorado in connection with Defendants' conduct. Compliance with

applicable Colorado statutes and regulations was also an express condition of payment of claims submitted to the State of Colorado.

145. As a result of Defendants' violation of Colo. Rev. Stat § 25.5-4-305, the State of Colorado has been damaged.

146. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to the Colorado Medical Assistance Act, Colo. Rev. Stat § 25.5-4-304 *et seq.* on behalf of herself and the State of Colorado.

147. This Court is requested to accept pendant jurisdiction over this related state claim as it is predicated upon the same exact facts as the federal claim, and merely asserts separate damages to the State of Colorado in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the State of Colorado:

(1) Three times the amount of actual damages which the State of Colorado has sustained as a result of Defendants' conduct;
(2) A civil penalty of up to $10,000 for each false claim which Defendants presented or caused to be presented to the State of Colorado;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to Colorado Medical Assistance Act, Colo. Rev. Stat § 25.5-4-304 et seq. and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT X
CONNECTICUT FALSE CLAIMS ACT

148. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 88 above as if fully set forth herein.

149. This is a *qui tam* action brought by Relator on behalf of the State of Connecticut to recover treble damages and civil penalties under the Connecticut False Claims Act, Public Act No. 09-5 et seq., signed by the Governor on October 5, 2009.

150. Defendants violated Conn. Public Act No. 09-5 § 2(a), which provides that no person shall:

> (1) Knowingly present, or cause to be presented, to an officer or employee of the state a false or fraudulent claim for payment or approval under medical assistance programs administrated by the Department of Social Services;
> (2) Knowingly make, or cause to be made or used a false record or statement to secure the payment by the state of a false or fraudulent claim under medical assistance programs administered by the Department of Social Services;
> (3) Conspire to defraud the state by securing the allowance of payment of a false claim under medical assistance programs administered by the Department of Social Services.

151. The State of Connecticut, by and through the Connecticut Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

152. Compliance with applicable Medicare, Medicaid and the various other federal laws

cited herein was an implied, and upon information and belief; also an express condition of payment of claims submitted to the State of Connecticut in connection with Defendants' conduct. Compliance with applicable Connecticut statutes, and regulations was also an express condition of payment of claims submitted to the State of Connecticut.

153. As a result of Defendants' violation of Conn. Public Act No. 09-5 § 2(a), the State of Connecticut has been damaged.

154. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Connecticut False Claims Act, Public Act No. 09-5 et seq. on behalf of herself and the State of Connecticut.

155. This Court is requested to accept pendant jurisdiction over this related state claim as it is predicated upon the same exact facts as the federal claim, and merely asserts separate damages to the State of Connecticut in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the State of Connecticut:

(1) Three times the amount of actual damages which the State of Connecticut has sustained as a result of Defendants' conduct;
(2) A civil penalty of up to $10,000 for each false claim which Defendants presented or caused to be presented to the State of Connecticut;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to Connecticut False Claims Act, Public Act No. 09-5 et seq. and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XI
DELAWARE FALSE CLAIMS AND REPORTING ACT

156. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 88 above as if fully set forth herein.

157. This is a *qui tam* action brought by Relator on behalf of the State of Delaware to recover treble damages and civil penalties under the Delaware False Claims and Reporting Act, Title 6, Chapter 12 of the Delaware Code.

158. Defendants violated 6 Del. C. § 1201(a), which provides liability for any person who:

> (1) knowingly presents, or causes to be presented, directly or indirectly, to an officer or employee of the Government a false or fraudulent claim for payment or approval;
> (2) knowingly makes, uses, or causes to be made or used, directly or indirectly, a false record or statement to get a false or fraudulent claim paid or approved; or
> (3) conspires to defraud the Government by getting a false or fraudulent claim allowed or paid.

159. The State of Delaware, by and through the Delaware Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

160. Compliance with applicable Medicare, Medicaid and the various federal laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Delaware in connection with Defendants' conduct. Compliance

with applicable Delaware statutes and regulations was also an express condition of payment of claims submitted to the State of Delaware.

161. As a result of Defendants' violation of 6 Del. C. § 1201(a), the State of Delaware has been damaged.

162. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to 6 Del. C. § 1203(b) on behalf of herself and the State of Delaware.

163. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Delaware in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the State of Delaware:

(1) Three times the amount of actual damages which the State of Delaware has sustained as a result of Defendants' conduct;
(2) A civil penalty of not less than $5,500 and not more than $11,000 for each false claim which Defendants caused to be presented to the State of Delaware;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to 6 Del C. § 1205, and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

COUNT XII
FLORIDA FALSE CLAIMS ACT

164. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 88 above as if fully set forth herein.

165. This is a *qui tam* action brought by Relator on behalf of the State of Florida to recover treble damages and civil penalties under the Florida False Claims Act, Fla. Stat. § 68.081 et seq.

166. Defendants violated Fla. Stat. § 68.082 (2), which provides liability for any person who:

> (a) knowingly presents or causes to be presented to an officer or employee of an agency a false or fraudulent claim for payment or approval;
> (b) knowingly makes, uses, or causes to be made or used a false record or statement to get a false or fraudulent claim paid or approved by an agency;
> (c) conspires to submit a false or fraudulent claim to an agency or to deceive an agency for the purpose of getting a false or fraudulent claim allowed or paid.

167. In addition, Fla. Stat. § 409.920 makes it a crime to:

> (c) knowingly charge, solicit, accept, or receive anything of value, other than an authorized copayment from a Medicaid recipient, from any source in addition to the amount legally payable for an item or service provided to a Medicaid recipient under the Medicaid program or knowingly fail to credit the agency or its fiscal agent for any payment received from a third-party source;
>
> * * *
>
> (e) knowingly, solicit, offer, pay or receive any remuneration, including any kickback, bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind, in return for referring an individual to a person for the furnishing of any item or service for which payment may be made, in whole or in part, under the Medicaid program, or in return for obtaining, purchasing, leasing, ordering, or arranging, for or recommending, obtaining, purchasing, leasing, or ordering any goods, facility,

item, or service, for which payment may be made, in whole or in part, under the Medicaid program.

168. The State of Florida, by and through the Florida Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

169. Compliance with applicable Medicare, Medicaid and the various federal laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Florida in connection with Defendants' conduct. Compliance with applicable Florida statutes and regulations was also an express condition of payment of claims submitted to the State of Florida.

170. As a result of Defendants' violation of Fla. Stat. § 68.082(2), the State of Florida has been damaged.

171. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Fla. Stat. § 68.083(2) on behalf of herself and the State of Florida.

172. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Florida in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the State of Florida:

(1) Three times the amount of actual damages which the State of Florida has sustained as a result of Defendants' conduct;
(2) A civil penalty of not less than $5,500 and not more than $11,000 for each false claim which Defendants caused to be presented to the State of Florida
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to Fla. Stat. § 68.085 and/or any other applicable provision of' law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action,
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XIII
GEORGIA FALSE MEDICAID CLAIMS ACT

173. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 88 above as if fully set forth herein.

174. This is a *qui tam* action brought by Relator on behalf of the State of Georgia to recover treble damages and civil penalties under the Georgia False Medicaid Claims Act, O.C.G.A. § 49-4-168 (2008) et seq.

175. Defendants violated O.C.G.A. § 49-4-168.1(a), which provides liability for any person who:

(1) knowingly presents, or causes to be presented to the Georgia Medicaid program a false or fraudulent claim for payment or approval;
(2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Georgia

Medicaid program;

(3) conspires to defraud the Georgia Medicaid program by getting a false or fraudulent claim allowed or paid.

176. The State of Georgia, by and through the Georgia Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

177. Compliance with applicable Medicare, Medicaid and the various federal laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Georgia in connection with Defendants' conduct. Compliance with applicable Georgia statutes and regulations was also an express condition of payment of claims submitted to the State of Georgia.

178. As a result of Defendants' violation of O.C.G.A. § 49-4-168, the State of Georgia has been damaged.

179. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to O.C.G.A. § 49-4-168 on behalf of herself and the State of Georgia.

180. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Georgia in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the State of Georgia:

(1) Three times the amount of actual damages which the State of Georgia has sustained as a result of Defendants' conduct;
(2) A civil penalty of not less than $5,500 and not more than $11,000 for each false claim which Defendants caused to be presented to the State of Georgia;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to O.C.G.A. § 49-4-168 and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XIV
HAWAII FALSE CLAIMS ACT

181. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 88 above as if fully set forth herein.

182. This is a *qui tam* action brought by Relator on behalf of the State of Hawaii to recover treble damages and civil penalties under the Hawaii False Claims Act, Haw. Rev. Stat. § 661-21 *et seq.*

183. Defendants violated Haw. Rev. Stat. § 661-21(a), which provides liability for any person who:

(1) knowingly presents, or causes to be presented, to an officer or employee of the state a false or fraudulent claim for payment or approval;
(2) knowingly makes, uses, or causes to be made or used, a false record or statement

> to get a false or fraudulent claim paid or approved by the state;
> (3) conspires to defraud the state by getting a false or fraudulent claim allowed or paid; or
>
> ***
>
> (8) is a beneficiary of an inadvertent submission of a false claim to the State, who subsequently discovers the falsity of the claim, and fails to disclose the false claim to the State within a reasonable time after discovery of the false claim.

184. The State of Hawaii, by and through the Hawaii Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

185. Compliance with applicable Medicare, Medicaid and the various federal laws cited herein was an implied, and upon information and belief; also an express condition of payment of claims submitted to the State of Hawaii in connection with Defendants' conduct. Compliance with applicable Hawaii statutes and regulations was also an express condition of payment of claims submitted to the State of Hawaii.

186. As a result of Defendants' violation of Haw. Rev. Stat. § 661-21(a) the State of Hawaii has been damaged.

187. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Haw. Rev. Stat. § 661-25(a) on behalf of herself and the State of Hawaii.

188. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Hawaii in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the State of Hawaii:

(1) Three times the amount of actual damages which the State of Hawaii has sustained as a result of Defendants' illegal conduct;
(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the State of Hawaii;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to Haw. Rev. Stat. § 661-27 and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XV
ILLINOIS WHISTLEBLOWER REWARD AND PROTECTION ACT

189. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 88 above as if fully set forth herein.

190. This is a *qui tam* action brought by Relator on behalf of the State of Illinois to recover treble damages and civil penalties under the Illinois Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. 175 *et seq*.

191. Defendants violated 740 Ill. Comp. Stat. 175/3(a), which provides liability for any person who:

(1) knowingly presents, or causes to be presented, to an officer or employee of the State of a member of the Guard a false or fraudulent claim for payment or approval;
(2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State;
(3) conspires to defraud the State by getting a false or fraudulent claim allowed or paid.

192. The State of Illinois, by and through the Illinois Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

193. Compliance with applicable Medicare, Medicaid and the various federal laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Illinois in connection with Defendants' conduct. Compliance with applicable Illinois statutes and regulations was also an express condition of payment of claims submitted to the State of Illinois.

194. As a result of Defendants' violation of 740 Ill. Comp. Stat. 175/3(a), the State of Illinois has been damaged.

195. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to 740 Ill Comp. Stat. 175/3(b) on behalf of herself and the State of Illinois.

196. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Illinois in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the State of Illinois:

(1) Three times the amount of actual damages which the State of Illinois has sustained as a result of Defendants' conduct;
(2) A civil penalty of not less than $5,500 and not more than $11,000 for each false claim which Defendants caused to be presented to the State of Illinois;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to 740 Ill. Comp. Stat.175/4(d) and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XVI
INDIANA FALSE CLAIMS AND WHISTLEBLOWER PROTECTION ACT

197. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 88 above as if fully set forth herein.

198. This is a *qui tam* action brought by Relator on behalf of the State of Indiana to recover treble damages and civil penalties under the Indiana False Claims and Whistleblower Protection Act, Ind. Code § 5-11-5.5 *et seq*.

Defendants violated Ind. Code § 5-11-5.5-2 (b) which provides liability for a person who knowingly or intentionally:

> (1) presents a false claim to the state for payment or approval;
> (2) makes or uses a false record or statement to obtain payment or approval of a false claim from the state;
> (3) with intent to defraud the state, delivers less money or property to the state than the amount recorded on the certificate or receipt the person receives from the state;
> (4) with intent to defraud the state, authorizes issuance of a receipt without knowing that the information on the receipt is true;
> (5) receives public property as a pledge of an obligation on a debt from an employee who is not lawfully authorized to sell or pledge the property;
> (6) makes or uses a false record or statement to avoid an obligation to pay or transmit property to the state;
> (7) conspires with another person to perform an act described in subdivisions (1) through (6); or
> (8) causes or induces another person to perform an act described in subdivisions (1) through (6)...

199. The State of Indiana, by and through the Indiana Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

200. Compliance with applicable Medicare, Medicaid and the various federal laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Indiana in connection with Defendants' conduct. Compliance with applicable Indiana statutes and regulations was also an express condition of payment of claims submitted to the State of Indiana.

201. As a result of Defendants' violation of Indiana Code 5-11-5.5 *et seq.*, the State of Indiana has been damaged.

202. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Indiana Code 5-11-5.5 *et seq.* on behalf of herself and the State of Indiana.

203. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Indiana in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the State of Indiana:

(1) Three times the amount of actual damages which the State of Indiana has sustained as a result of Defendants' conduct;
(2) A Civil penalty of at least five thousand dollars ($5,000) and for up to three (3) times the amount of damages sustained by the State of Indiana;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to Indiana Code 5-11-5.5 et seq. and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XVII
LOUISIANA MEDICAL ASSISTANCE PROGRAMS INTEGRITY LAW

204. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 88 above as if fully set forth herein.

205. This is a *qui tam* action brought by Relator on behalf of the State of Louisiana to recover treble damages and civil penalties under the Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. 46: 437.1 *et seq*.

206. Defendants violated La. Rev. Stat. 46: 438.3, which provides:

> (A) No person shall knowingly present or cause to be presented a false or fraudulent claim;
> (B) No person shall knowingly engage in misrepresentation to obtain, or attempt to obtain, payment from medical assistance program funds;
> (C) No person shall conspire to defraud, or attempt to defraud, the medical assistance programs through misrepresentation or by obtaining, or attempting to obtain, payment for a false or fraudulent claim;

207. The State of Louisiana, by and through the Louisiana Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

208. Compliance with applicable Medicare, Medicaid and the various federal laws cited herein was an implied, and upon information and belief, also an express condition of payment of

claims submitted to the State of Louisiana in connection with Defendants' conduct. Compliance with applicable Louisiana statutes and regulations was also an express condition of payment of claims submitted to the State of Louisiana.

209. As a result of Defendants' violation of La. Rev. Stat. 46: 438.3, the State of Louisiana has been damaged.

210. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to La. Rev. Stat. 46: 439.1(A) on behalf of herself and the State of Louisiana.

211. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Louisiana in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the State of Louisiana:

(1) Three times the amount of actual damages which the State of Louisiana has sustained as a result of Defendants' conduct;
(2) A civil penalty of up to $10,000 for each false claim which Defendants caused to be presented to the State of Louisiana;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to La. Rev. Stat. § 439.4(A) and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XVIII
MICHIGAN MEDICAID FALSE CLAIMS ACT

212. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 88 above as if fully set forth herein.

213. This is a *qui tam* action brought by Relator on behalf of the State of Michigan to recover treble damages and civil penalties under the Michigan Medicaid False Claims Act. Mich. Comp. Laws § 400.603 *et seq.*

214. Defendants violated Mich. Comp. Laws § 400.603, which provides liability in pertinent part as follows:

> Sec. 3. (1) A person shall not knowingly make or cause to be made a false statement or false representation of a material fact in an application for Medicaid benefits;
> (2)A person shall not knowingly make or cause to be made a false statement or false representation of a material fact for use in determining rights to a Medicaid benefit...

215. The State of Michigan, by and through the Michigan Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

216. Compliance with applicable Medicare, Medicaid and the various federal laws cited herein was an implied, and upon information and belief, also an express condition of payment of

claims submitted to the State of Michigan in connection with Defendants' conduct. Compliance with applicable Michigan statutes and regulations was also an express condition of payment of claims submitted to the State of Michigan.

217. As a result of Defendants' violation of MI ST Ch. 400.603 et seq. the State of Michigan has been damaged.

218. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to MI ST Ch. 400.603 et seq. on behalf of herself and the State of Michigan.

219. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Michigan in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the State of Michigan:

(1) Three times the amount of actual damages which the State of Michigan has sustained as a result of Defendants' conduct;
(2) A civil penalty equal to the full amount received for each false claim which Defendants caused to be presented to the State of Michigan;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to MI ST Ch. 400.603 et seq. and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XIX
MINNESOTA FALSE CLAIMS ACT

220. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 88 above as if fully set forth herein.

221. This is a *qui tam* action brought by Relator on behalf of the State of Minnesota to recover treble damages and civil penalties under the Minnesota False Claims Act, Minn. Stat. § 15C.01, *et seq*.

222. Defendants violated Minn. Stat. § 15C.02, which provides civil liability for any person who:

> (1) knowingly presents, or causes to be presented, to an officer or employee of the state or a political subdivision a false or fraudulent claim for payment or approval;
>
> (2) knowingly makes or uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the state or a political subdivision;
>
> (3) knowingly conspires to either present a false or fraudulent claim to the state or a political subdivision for payment or approval or makes, uses, or causes to be made or used a false record or statement to obtain payment or approval of a false or fraudulent claim;...

223. The State of Minnesota, by and through the Minnesota False Claims Act program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by

healthcare providers and third party payers in connection therewith.

224. Compliance with applicable Medicare, Medicaid and the various federal laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Minnesota in connection with Defendants' conduct. Compliance with applicable Minnesota statutes and regulations was also an express condition of payment of claims submitted to the State of Minnesota.

225. As a result of Defendants' violation of Minn. Stat. § 15C.01, et seq. the State of Minnesota has been damaged.

226. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Minn. Stat. § 15C.01, et seq. on behalf of herself and the State of Minnesota.

227. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Minnesota in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the State of Minnesota:

(1) Three times the amount of actual damages which the State of Minnesota has sustained as a result of Defendants' conduct;
(2) A civil penalty equal to the full amount received for each false claim which Defendants caused to be presented to the State of Minnesota;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to Minn. Stat. § 15C.01, et seq. and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XX
NEVADA FALSE CLAIMS ACT

228. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 88 above as if fully set forth herein.

229. This is a *qui tam* action brought by Relator on behalf of the State of Nevada to recover treble damages and civil penalties under the Nevada False Claims Act, Nev. Rev. Stat. § 357.010, *et seq*.

230. Defendants violated Nev. Rev. Stat. § 357.040(1), which provides liability for any person who:

> (a) knowingly presents or causes to be presented a false claim for payment or approval;
> (b) knowingly makes or uses, or causes to be made or used, a false record or statement to obtain payment or approval of a false claim
> (c) conspires to defraud by obtaining allowance or payment of a false claim;
> ***
> (h) is a beneficiary of an inadvertent submission of a false claim and, after discovering the falsity of the claim, fails to disclose the falsity to the state or political subdivision within a reasonable time.

231. The State of Nevada, by and through the Nevada Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

232. Compliance with applicable Medicare, Medicaid and the various federal laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Nevada in connection with Defendants' conduct. Compliance with applicable Nevada statutes and regulations was also an express condition of payment of claims submitted to the State of Nevada.

233. As a result of Defendants' violation of Nev. Rev. Stat. § 357.040(1) the State of Nevada has been damaged.

234. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Nev. Rev. Stat. § 357.080(1) on behalf of herself and the State of Nevada.

235. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Nevada in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the State of Nevada:

(1) Three times the amount of actual damages which the State of Nevada has sustained as a result of Defendants' conduct;

(2) A civil penalty of not less than $2,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the State of Nevada;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to Nev. Rev. Stat. § 357.210 and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XXI
NEW JERSEY FALSE CLAIMS ACT

236. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 88 above as if fully set forth herein.

237. This is a *qui tam* action brought by Relator on behalf of the State of New Jersey to recover treble damages and civil penalties under the New Jersey False Claims Act, N.J. Stat. § 2A:32C-1 et seq. (2008) *et seq.*

238. Defendants violated N.J. Stat. § 2A:32C-3, which provides liability for any person who:

(a) knowingly presents, or causes to be presented, to an employee, officer, or agent of the State or to any contractor, grantee, or other recipient of State funds, a false or fraudulent claim for payment or approval;
(b) knowingly makes, uses, or causes to be made or used a false record or statement to get a false or fraudulent claim paid or approved by the State;
(c) conspires to defraud the State by getting a false or fraudulent claim allowed or paid by the State.

239. The State of New Jersey, by and through the New Jersey Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

240. Compliance with applicable Medicare, Medicaid and the various federal laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of New Jersey in connection with Defendants' conduct. Compliance with applicable New Jersey statutes and regulations was also an express condition of payment of claims submitted to the State of New Jersey.

241. As a result of Defendants' violation of N.J. Stat. § 2A:32C-1 et seq., the State of New Jersey has been damaged.

242. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to N.J. Stat. § 2A:32C-1 et seq. on behalf of herself and the State of New Jersey.

243. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of New Jersey in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the State of New Jersey:

(1) Three times the amount of actual damages which the State of New Jersey has sustained as a result of Defendants' conduct;
(2) A civil penalty of not less than and not more than the civil penalty allowed under the federal False Claims Act (31 U.S.C. s.3729 et seq.) which Defendants caused to be presented to the State of New Jersey;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to N.J. Stat. § 2A:32C-1 et seq. and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XXII
NEW MEXICO MEDICAID FALSE CLAIMS ACT AND NEW MEXICO FRAUD AGAINST TAXPAYERS ACT

244. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 88 above as if fully set forth herein.

245. This is a *qui tam* action brought by Relator on behalf of the State of New Mexico to recover treble damages and civil penalties under the New Mexico Medicaid False Claims Act N.M. Stat. Ann §§ 27-14-1 *et seq.*

246. Defendants violated N.M. Stat. Ann §§ 27-14-1 Section 4, which provides liability in pertinent part as follows:

A person ...shall be liable...if the person:

> A. presents, or causes to be presented, to the state a claim for payment under the Medicaid program knowing that such claim is false or fraudulent;
> B. presents, or causes to be presented, to the state a claim for payment under the Medicaid program knowing that the person receiving a Medicaid benefit or payment is not authorized or is not eligible for a benefit under the Medicaid program;
> C. makes, uses or causes to be made or used a record or statement to obtain a false or fraudulent claim under the Medicaid program paid for or approved by the state knowing such record or statement is false;
> D. conspires to defraud the state by getting a claim allowed or paid under the Medicaid program knowing that such claim is false or fraudulent;

247. It is also brought by Relator on behalf of the State of New Mexico to recover treble damages and civil penalties under the New Mexico Fraud Against Taxpayers Act N.M. Stat. Ann § 44-9-1 et seq.

248. New Mexico Fraud Against Taxpayers Act N.M. Stat. Ann § 44-9-1 et seq. provides:

§ 44-9-3(A) A person shall not:

> (1) knowingly present, or cause to be presented, to an employee, officer or agent of the state or to a contractor, grantee or other recipient of state funds a false or fraudulent claim for payment or approval;
> (2) knowingly make or use, or cause to be made or used, a false, misleading or fraudulent record or statement to obtain or support the approval of or the payment on a false or fraudulent claim;
> (3) conspire to defraud the state by obtaining approval or payment on a false or fraudulent claim;

249. The State of New Mexico, by and through the New Mexico Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

250. Compliance with applicable Medicare, Medicaid and the various federal laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of New Mexico in connection with Defendants' conduct. Compliance with applicable New Mexico statutes and regulations was also an express condition of payment of claims submitted to the State of New Mexico.

251. As a result of Defendants violation of N.M. Stat. Ann §§ 27-14-1 et seq. the State of New Mexico has been damaged.

252. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to N.M. Stat. Ann §§ 27-14-1 et seq. on behalf of herself and the State of New Mexico.

253. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of New Mexico in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the State of New Mexico:

(1) Three times the amount of actual damages which the State of New Mexico has sustained as a result of Defendants' conduct;
(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the State of New Mexico;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to N.M. Stat. Ann §§ 27-14-1 et seq. and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XXIII
NEW YORK FALSE CLAIMS ACT

254. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 88 above as if fully set forth herein.

255. This is a *qui tam* action brought by Relator on behalf of the State of New York to recover treble damages and civil penalties under the New York False Claims Act, 2007 N.Y. Laws 58, Section 39, Article XIII

256. Defendants violated 2007 N.Y. Laws 58, Section 39, Article XIII Section 189, which provides liability for any person who:

> (a) knowingly presents, or causes to be presented, to any employee, officer or agent of the state or local government, a false or fraudulent claim for payment or approval;
> (b) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the state or local government;
> (c) conspires to defraud the State by getting a false or fraudulent claim allowed or paid.

257. The State of New York, by and through the New York Medicaid program and other

state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

258. Compliance with applicable Medicare, Medicaid and the various federal laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of New York in connection with Defendants' conduct. Compliance with applicable New York statutes and regulations was also an express condition of payment of claims submitted to the State of New York.

259. As a result of Defendants' violation of 2007 N.Y. Laws 58, Section 39, Article XIII, the State of New York has been damaged.

260. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to 2007 N.Y. Laws 58, Section 39, Article XIII, on behalf of herself and the State of New York.

261. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of New York in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the State of New York:

(1) Three times the amount of actual damages which the State of New York has sustained as a result of Defendants' conduct;
(2) A civil penalty of not less than $6,000 and not more than $12,000 for each false claim which Defendants caused to be presented to the State of New

York;

(3) Prejudgment interest; and

(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to 2007 N.Y. Laws 58, Section 39, Article XIII, and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

COUNT XXIV
NORTH CAROLINA FALSE CLAIMS ACT

262. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 88 above as if fully set forth herein.

263. This is a *qui tam* action brought by Relator on behalf of the State of North Carolina to recover treble damages and civil penalties under the North Carolina False Claims Act, N.C. Gen. Stat. §§ 1-605 *et seq.*

264. Defendants violated N.C. Gen. Stat. § 1-607(a), which provides liability for any person who:

(1) Knowingly presents or causes to be presented a false or fraudulent claim for payment or approval;

(2) Knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;

(3) Conspires to commit a violation of subdivision (1), (2), (4), (5), (6), or (7) of this section;

***

(7) Knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the State, or knowingly conceals or knowingly and improperly avoids or decreases an obligation

to pay or transmit money or property to the State.

265. The State of North Carolina, by and through the North Carolina Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

266. Compliance with applicable Medicare, Medicaid and the various federal laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of North Carolina in connection with Defendants' conduct. Compliance with applicable North Carolina statutes and regulations was also an express condition of payment of claims submitted to the State of North Carolina.

267. As a result of Defendants' violation of N.C. Gen. Stat. § 1-605 et seq., and its anti kickback statutes, the State of North Carolina has been damaged.

268. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to N.C. Gen. Stat. § 1-605(b) on behalf of herself and the State of North Carolina.

269. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of North Carolina in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the State of North Carolina:

(1) Three times the amount of actual damages which the State of North Carolina has sustained as a result of Defendants' conduct;
(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the State of North Carolina;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to N.C. Gen. Stat. § 1-605 et seq. and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XXV
OKLAHOMA MEDICAID FALSE CLAIMS ACT

270. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 88 above as if fully set forth herein.

271. This is a *qui tam* action brought by Relator on behalf of the State of Oklahoma to recover treble damages and civil penalties under the Oklahoma Medicaid False Claims Act 63 Okl. St. § 5053 (2008) *et seq*.

272. Defendants violated 63 Okl. St. § 5053.1 (2)(B), which provides liability for any person who:

(1) knowingly presents, or causes to be presented, to an officer or employee of the State of Oklahoma, a false or fraudulent claim for payment or approval;

(2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State;
(3) conspires to defraud the State by getting a false or fraudulent claim allowed or paid.

273. The State of Oklahoma, by and through the Oklahoma Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

274. Compliance with applicable Medicare, Medicaid and the various federal laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Oklahoma in connection with Defendants' conduct. Compliance with applicable Oklahoma statutes and regulations was also an express condition of payment of claims submitted to the State of Oklahoma.

275. As a result of Defendants' violation of 63 Okl. St. § 5053.1 et seq., the State of Oklahoma has been damaged.

276. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to 63 Okl. St. § 5053.1 et seq. on behalf of herself and the State of Oklahoma.

277. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Oklahoma in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to

the following parties and against Defendants:

To the State of Oklahoma:

(1) Three times the amount of actual damages which the State of Oklahoma has sustained as a result of Defendants' conduct;
(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the State of Oklahoma;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to 63 Okl. St. § 5053.1 et seq. and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XXVI
RHODE ISLAND STATE FALSE CLAIMS ACT

278. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 88 above as if fully set forth herein.

279. This is a *qui tam* action brought by Relator on behalf of the State of Rhode Island to recover treble damages and civil penalties under the Rhode Island State False Claims Act R.I.Gen. Laws § 9-1.1-1 (2008) *et seq.*

280. Defendants violated R.I. Gen. Laws § 9-1.1-3, which provides liability for any person who:

(1) knowingly presents, or causes to be presented, to an officer or employee of the State or a member of the Guard a false or fraudulent claim for payment or approval;
(2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State;
(3) conspires to defraud the State by getting a false or fraudulent claim allowed or paid.

281. The State of Rhode Island, by and through the Rhode Island Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

282. Compliance with applicable Medicare, Medicaid and the various federal laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Rhode Island in connection with Defendants' conduct. Compliance with applicable Rhode Island statutes and regulations was also an express condition of payment of claims submitted to the State of Rhode Island.

283. As a result of Defendants' violation of R.I. Gen. Laws § 9-1.1-1, the State of Rhode Island has been damaged.

284. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to R.I. Gen. Laws § 9-1.1-1 et seq. on behalf of herself and the State of Rhode Island.

285. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Rhode Island in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the State of Rhode Island:

(1) Three times the amount of actual damages which the State of Rhode Island has sustained as a result of Defendants' conduct;
(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the State of Rhode Island;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to R.I. Gen. Laws § 9-1.1-1 and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XXVII
TENNESSEE FALSE CLAIMS ACT

286. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 88 above as if fully set forth herein.

287. This is a *qui tam* action brought by Relator on behalf of the State of Tennessee to recover treble damages and civil penalties under the Tennessee False Claims Act, Tenn. Code Ann. § 4-18-101 *et seq.* and Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-181 *et seq.*

288. Defendants violated Tenn. Code Ann§ 4-18-103(a), which provides liability for any person who:

> (1) Knowingly presents, or causes to be presented to an officer or employee of the state..., a false claim for payment or approval;
> (2) Knowingly makes, uses, or causes to be made or used, a false record or statement to get a false claim paid or approved by the state or by any political subdivision;
> (3) Conspires to defraud the state or any political subdivision by getting a claim allowed or paid by the state of by any political subdivision.
>
> § 71-5-182(a)(1) provides liability for any person who-
>
> (A) presents, or causes to be presented to the state, a claim for payment under the Medicaid program knowing such claim is false or fraudulent;
> (B) makes or uses, or causes to be made or used, a record or statement to get a false or fraudulent claim under the Medicaid program paid for or approved by the state knowing such record or statement is false;
> (C) conspires to defraud the State by getting a claim allowed or paid under the Medicaid program knowing such claim is false or fraudulent.

289. The State of Tennessee, by and through the Tennessee Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

290. Compliance with applicable Medicare, Medicaid and the various federal laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Tennessee in connection with Defendants' conduct. Compliance with applicable Tennessee statutes and regulations was also an express condition of payment of claims submitted to the State of Tennessee.

291. As a result of Defendants' violation of Tenn. Code Ann. § 4-18-103(a) and § 71-5-182(a)(1), the State of Tennessee has been damaged.

292. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Tenn. Code Ann. § 4-18-103(a) and § 71-5-183(a)(1) on behalf themselves and the State of Tennessee.

293. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Tennessee in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the State of Tennessee:

(1) Three times the amount of actual damages which the State of Tennessee has sustained as a result of Defendants' conduct;
(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the State of Tennessee;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to Tenn. Code Ann. § 71-5-183 (c) and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XXVII
TEXAS MEDICAID FRAUD PREVENTION LAW

294. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 88 above as if fully set forth herein.

295. This is a *qui tam* action brought by Relator on behalf of the State of Texas to recover double damages and civil penalties under Tex. Hum. Res. Code § 36.001 *et seq.*

296. Defendants violated Tex. Hum. Res. Code § 36.002, which provides liability for any person who:

> (1) knowingly or intentionally makes or causes to be made a false statement or misrepresentation of a material fact:
> (a) on an application for a contract, benefit, or payment under the Medicaid program; or
> (b) that is intended to be used to determine its eligibility for a benefit
>
> (2) knowingly or intentionally concealing or failing to disclose an event:
> (A) that the person knows affects the initial or continued right to a benefit or payment under the Medicaid program of.
> (i) the person, or
> (ii) another person on whose behalf the person has applied for a benefit or payment or is receiving a benefit or payment; and
> (B) to permit a person to receive a benefit or payment that is not authorized or that is greater than the payment or benefit that is authorized;
>
> ***
>
> (4) knowingly or intentionally makes, causes to be made, induces, or seeks to induce the making of a false statement or misrepresentation of material fact concerning:
> (B) information required to be provided by a federal or state law, rule, regulation, or provider agreement pertaining to the Medicaid program;
>
> (5) ... knowingly or intentionally charges, solicits, accepts, or receives, in addition to an amount paid under the Medicaid program, a gift, money, a

> donation, or other consideration as a condition to the provision of a service or continued service to a Medicaid recipient if the cost of the service provided to the Medicaid recipient is paid for, in whole or in part, under the Medicaid program.

297. The State of Texas, by and through the Texas Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

298. Compliance with applicable Medicare, Medicaid and the various federal laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Texas in connection with Defendants' conduct. Compliance with applicable Texas statutes and regulations was also an express condition of payment of claims submitted to the State of Texas.

299. As a result of Defendants' violation of Tex. Hum. Res. Code § 36.002, the State of Texas has been damaged.

300. Defendants did not, within 30 days after it first obtained information as to such violation, furnish such information to officials of the State responsible for investigating false claims violation, did not otherwise fully cooperate with any investigation of the violation, and have not otherwise furnished information to the State regarding the claims for reimbursement at issue.

301. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Tex. Hum. Res. Code § 36.101 on behalf of herself and the State of Texas.

302. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Texas in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the State of Texas:

(1) Two times the amount of actual damages which the State of Texas has sustained as a result of Defendants' conduct;
(2) A civil penalty of not less than $5,000 or more than $15,000 pursuant to Tex. Hum. Res. Code § 36.025(a)(3) for each false claim which Defendants cause to be presented to the state of Texas;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to Tex. Hum. Res. Code § 36.110, and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XXIX
WISCONSIN FALSE CLAIMS FOR MEDICAL ASSISTANCE ACT

303. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 88 above as if fully set forth herein.

304. This is a *qui tam* action brought by Relator on behalf of the State of Wisconsin to recover treble damages and civil penalties under the Wisconsin False Claims for Medical Assistance

Law, Wis. Stat. § 20.931 *et seq*.

305. Defendants violated Wis. Stat. § 20.931(2), which provides liability for any person who:

> (a) Knowingly presents or causes to be presented to any officer, employee, or agent of this state a false claim for medical assistance.
>
> (b) Knowingly makes, uses, or causes to be made or used a false record or statement to obtain approval or payment of a false claim for medical assistance.
>
> (c) conspires to defraud this State by obtaining allowance or payment of claim for medical assistance, or by knowingly making or using, or causing to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Medical Assistance Program;
>
> ***
>
> (g) knowingly makes, uses or causes to be made or used a false record or statement to conceal, avoid, or decrease any obligation to pay or transmit money or property to the Medical Assistance Program.

306. The State of Wisconsin, by and through the Wisconsin Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

307. Compliance with applicable Medicare, Medicaid and the various federal laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Wisconsin in connection with Defendants' conduct. Compliance with applicable Wisconsin statutes and regulations was also an express condition of payment of claims submitted to the State of Wisconsin.

308. As a result of Defendants' violation of Wis. Stat. § 20.931 et seq. , the State of

Wisconsin has been damaged.

309. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Wis. Stat. § 20.931 et seq. on behalf of herself and the State of Wisconsin.

310. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Wisconsin in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the State of Wisconsin:

(1) Three times the amount of actual damages which the State of Wisconsin has sustained as a result of Defendants' conduct;
(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the State of Wisconsin;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to Wis. Stat. § 20.931 and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XXX
MASSACHUSETTS FALSE CLAIMS ACT

311. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 88 above as if fully set forth herein.

312. This is a *qui tam* action brought by Relator on behalf of the Commonwealth of Massachusetts for treble damages and penalties under Massachusetts False Claims Act, Mass. Gen. Laws Chap. 12 § 5(A) *et seq*.

313. Defendants violated Mass. Gen. Laws Chap. 12 § 5B, whichprovides liability for any person who:

> (1) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
> (2) knowingly makes, uses, or causes to be made or used, a false record or statement to obtain payment or approval of a claim by the commonwealth or ...
> (3) conspires to defraud the commonwealth or any political subdivision thereof through the allowance or payment of a fraudulent claim;
> ***
> (9) is a beneficiary of an inadvertent submission of a false claim to the commonwealth or political subdivision thereof, subsequently discovers the falsity of the claim, and fails to disclose the false claim to the commonwealth or political subdivision within a reasonable time after discovery of the false claim shall be liable to the commonwealth or political subdivision.

314. The Commonwealth of Massachusetts, by and through the Massachusetts Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

315. Compliance with applicable Medicare, Medicaid and the various federal laws cited herein was an implied, and upon information and belief: also an express condition of payment of

claims submitted to the Commonwealth of Massachusetts in connection with Defendants' conduct. Compliance with applicable Massachusetts statutes and regulationswas also an express condition of payment of claims submitted to the Commonwealth of Massachusetts.

316. As a result of Defendants' violation of Mass. Gen. Laws Chap. 12 § 5B, the Commonwealth of Massachusetts has been damaged.

317. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Mass. Gen. Laws Chap. 12 § 5(c)(2) on behalf of herself and the Commonwealth of Massachusetts.

318. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the Commonwealth of Massachusetts in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the Commonwealth of Massachusetts:

(1) Three times the amount of actual damages which the Commonwealth of Massachusetts has sustained as a result of Defendants' conduct;
(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the Commonwealth of Massachusetts;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to Mass. Gen. Laws Chap. 12, § 5F and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XXXI
VIRGINIA FRAUD AGAINST TAXPAYERS ACT

319. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 88 above as if fully set forth herein.

320. This is a *qui tam* action brought by Relator on behalf of the Commonwealth of Virginia for treble damages and penalties under Virginia Fraud Against Taxpayers Act § § 01-216.1 *et seq*.

321. Defendants violated Va. Code Ann. § 8.01-216.3A, which provides liability for any person who:

1. Knowingly presents, or causes to be presented, to an officer or employee of the Commonwealth a false or fraudulent claim for payment or approval;
2. Knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Commonwealth;
3. Conspires to defraud the Commonwealth by getting a false or fraudulent claim allowed or paid;

322. The Commonwealth of Virginia, by and through the Virginia Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

323. Compliance with applicable Medicare, Medicaid and the various federal laws cited

herein was an implied, and upon information and belief; also an express condition of payment of claims submitted to the Commonwealth of Virginia in connection with Defendants' conduct. Compliance with applicable Virginia statutes and regulations was also an express condition of payment of claims submitted to the Commonwealth of Virginia.

324. As a result of Defendants' violation of Va. Code Ann. § 8.01-216.3(A), the Commonwealth of Virginia has been damaged.

325. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Va. Code Ann. § 8.01-216.3 et seq. on behalf of herself and the Commonwealth of Virginia.

326. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the Commonwealth of Virginia in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the Commonwealth of Virginia:

(1) Three times the amount of actual damages which the Commonwealth of Virginia has sustained as a result of Defendants' conduct;
(2) A civil penalty of not less than $5,500 and not more than $11,000 for each false claim which Defendants caused to be presented to the Commonwealth of Virginia;
(3) Prejudgment interest; and
(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to Va. Code Ann. § 32.1-315 and/or any other applicable provision of law;
(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;
(3) An award of reasonable attorneys' fees and costs; and
(4) Such further relief as this Court deems equitable and just.

COUNT XXXII
DISTRICT OF COLUMBIA PROCUREMENT REFORM AMENDMENT ACT

327. Plaintiff repeats and realleges each allegation contained in paragraphs 1 through 88 above as if fully set forth herein.

328. This is a *qui tam* action brought by Relator and the District of Columbia to recover treble damages and civil penalties under the District of Columbia Procurement Reform Amendment Act, D.C. Code § 2-308.13 *et seq*.

329. Defendants violated D.C. Code § 2-308.14(a), which provides liability for any person who:

> (1) knowingly presents, or causes to be presented, to an officer or employee of the District a false claim for payment or approval;
> (2) knowingly makes, uses, or causes to: be made or used, a false record or statement to get a false claim paid or approved by the District;
> (3) conspires to defraud the District by getting a false claim allowed or paid by the District;
> ***
> (8) is the beneficiary of an inadvertent submission of a false claim to the District, subsequently discovers the falsity of the claim, and fails to disclose the false claim to the District.

330. The District of Columbia, by and through the District of Columbia Medicaid program

and other state healthcare programs, and unaware of Defendants' illegal conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

331. Compliance with applicable Medicare, Medicaid and the various federal laws cited herein was an implied, and upon information and belief; also an express condition of payment of claims submitted to the District of Columbia in connection with Defendants' illegal conduct. Compliance with applicable D.C. statutes and regulations was also an express condition of payment of claims submitted to the District of Columbia.

332. As a result of Defendants' violation of D.C. Code § 2-308.14(a) the District of Columbia has been damaged.

333. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to D.C. Code § 2-308.15(b) on behalf of herself and the District of Columbia.

334. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the District of Columbia in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the District of Columbia:

(1) Three times the amount of actual damages which the District of Columbia has sustained as a result of Defendants' illegal conduct;
(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim which Defendants caused to be presented to the District of

Columbia;

(3) Prejudgment interest; and

(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to D.C. Code § 2-308.15(f) and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

DATED this 17th day of November, 2011.

Respectfully Submitted,

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